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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1991

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

Part 2 (Pages 1-1209)

Department of Health and Human Services

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1991

WEDNESDAY, FEBRUARY 7, 1990

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Burdick, Bumpers, Specter, and Cochran.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. LOUIS W. SULLIVAN, SECRETARY

BUDGET REQUEST

Senator HARKIN. Good morning. The Subcommittee on Labor, Health and Human Services, Education and related agencies will come to order.

I want to welcome Secretary Sullivan here this morning to review with us the fiscal year 1991 budget for his Department. The fiscal year 1991 total request for the portion of the Department which is under the jurisdiction of this subcommittee is $135,623,000,000 of which $19,546,000,000 is for discretionary programs, $116,077,000,000 is for mandatory programs for which this subcommittee has very little control. This is a total increase of $11.2 billion or 9 percent, although the discretionary programs are only increased by 3 percent.

In addition, in fiscal year 1991 the Department will spend an estimated $329 billion from the permanent trust funds, so this will bring the total annual spending in fiscal year 1991 to a total of about $464 billion representing 38 percent of the entire Federal spending.

This morning's hearing will be followed by three additional hearings to examine in greater detail the requests of various agencies in the Department of Health and Human Services.

This morning will give us an opportunity to review with the Secretary some major matters of broad policy significance.

I was pleased, Mr. Secretary, to see the Department's budget give increased emphasis and focus to health programs which affect minority populations. The minority health legislation passed by the Congress last year is all but fully funded in the Secretary's budget. I want to compliment you on the leadership that you have shown in that regard.

I do, however, continue to have concerns with the lack of full attention focused on matters of rural health care. I was particularly concerned to see the Department discontinue funding for the Rural Health Transition Grant Program which is very meaningful because a lot of these small hospitals out there, Dr. Sullivan, must change their old methods of operations if they are going to be viable entities in those communities.

Those transition grants would have helped them go from a full-time acute care facility to a facility that may encompass a lot of other types of support activities regarding health and human services in the local community. Those transition grants were very important to those hospitals, and I am greatly disappointed that they are going unfunded.

With regard to the AIDS epidemic, the Department has once again chose not to request funding for AZT and has requested no funding for the AIDS home health care and the subacute care programs which we funded in 1990. Small amounts, but at least a beginning. With the recent FDA findings which have approved the use of AZT for those infected with HIV virus but who have not yet developed AIDS, and the FDA approval of the use of AZT for children with AIDS, we expect the demand for AZT to be greatly expanded. And if there is no funding in this program and we are up against budget crunches, then that puts us in quite a bind.

Also, the administration does not seem to have a policy or program in place to deal with the need for AZT and other AIDS drugs for that indigent population which cannot afford them.

An overarching concern is the concern we all share in bringing down the escalating costs of health care in America. I brought a couple of charts, Dr. Sullivan, to draw your attention to a couple of items.

The first chart on my left with the bar graph shows two things. On the left-hand side it ranks the per capita health care expenditures by country. The right-hand column ranks the percent by which the U.S. exceeds that country in per capita health care expenditures. So, as you can see, the United States is No. 1 in per capita expenditures at $2,051—and again, we are going back 2 years on this, so this is the most recent data that we have.

Canada, our neighbor to the north, is next highest at $1,483 yet, we exceed the expenditures of Canada by 38 percent, one-third higher. But in Canada everyone is covered, everyone. And last year Canada only had 37 malpractice suits. How many did we have in America? Tens of thousands, probably.

When I look at these charts I think the Canadians are not all that much different than we are, and then you look down at some of the other countries which we exceed and it is just incredible.

When you compare the chart on the left with the chart on the right, the chart on the right shows the growth in health care expenditures from 1965 to 1988. We use 1965 as a base year, assign it as 100. Basically what this shows is that national health care expenditures as we all know are going up three times as fast as the CPI, three times as fast, with no signs of abating whatsoever.

So, this all threatens us. It threatens to bankrupt our efforts to bring the deficit under control, bankrupt personal finances, and I want to continue to work with you, Mr. Secretary, to find ways to reduce program costs without causing serious damage to the necessary services that government provides.

We have to find additional efficiencies someplace, eliminate duplication and overlap, eliminate fraud and wasteful spending. And I might venture forth in one other area. I think we need to correct programs that unnecessarily shift costs toward the Federal Government when the State and local governments might legitimately pick up a greater share of that cost, and I will go over some of those with you in a bit.

Mr. Secretary, I look forward to our discussion this morning, I look forward to working with you again this year in developing a budget that we can all support. Finally, Mr. Secretary, I call your attention to a question I will raise with the Family Support Administration concerning the growing Federal loss in the child support enforcement program and I will get into that with you during the questioning period.

So again, welcome. I congratulate you on a very good first year. I was delighted to see you appeal the first budget estimates that came down in December. I thought it was great of you to do that, and it came back better than what it was in the initial stages.

So, at this point I would like to yield to my distinguished colleague and ranking member, Senator Specter, for any opening statement he would like to make.

OPENING STATEMENT OF ARLEN SPECTER

Senator **Specter**. Thank you, Mr. Chairman.

Mr. Secretary, I join the chairman in welcoming you here and congratulating you on a good first year.

As we look at the categories which are under the direction of your department, it is staggering, but there is so much to be done and so little to do it with. We see the costs of health care in this country in the range of $600 billion, about 12 percent of the gross national product, and the cost escalating, and we know that there are millions of Americans uninsured. It costs billions of dollars, and the President has given you the task of a proposal to try to meet those needs, and it is enormous.

We have just finished last year's budget, and Senator Harkin and I and others wrestled on the Senate floor and made adjustments and transfers, and we have obligations from some of those transfers from last year, and now we start the process again and look at an enormous number of needs.

We confront the most difficult problems of our society, the problem of drugs, which your department has a major role in, detoxification and the homeless, and the problem of lead poisoning and big improvements in Gaucher's disease, needing additional funding. There is a small increase for the National Institutes of Health, a small increase for mental health research. We have to find, somehow, somewhere, some way more moneys for these matters.

I compliment you, Mr. Secretary, on speaking out on the effort to market a new cigarette directed at blacks in America. In the context of the problem of addiction for profit, a new direction was made there, and without 1 cent in cost to the Federal Government, or the taxpayers, with a very effective jawbone, you were able to stop that kind of a program. I think that is a sign as to what can be done by effective advocacy for someone who is willing to move to the forefront and take a tough, controversial position and make it stick.

A year ago there were a lot of difficulties besetting your situation as we moved through the confirmation process, and you have come through that with real leadership. I think that you, with our help, will be up to the job of making ends meet here somehow, some way. However, as I look over the list of needs in your department and look over the available funds, it is going to be a difficult task to work our way through to a conference report, such as the one we tackled late in last year's session, and to try to make ends meet.

But this is the starting point. We are glad to see you here, and we will work with you as best we can to fulfill those obligations.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Specter.

Any other opening statements?

Senator Burdick.

Senator BURDICK. I have no opening statement. I have a series of questions when the times comes.

Senator HARKIN. Do you have an opening statement, Senator Bumpers?

Senator BUMPERS. I have no opening statement.

Senator HARKIN. Thank you.

Secretary, welcome. Please proceed with your statement.

Secretary SULLIVAN. Thank you very much, Chairman Harkin, Senator Specter, and members of the committee. It is a pleasure to appear before you this morning to discuss our Department's proposal for fiscal year 1991, and I point out that the total budget for the year that we are proposing is $464 billion, an increase of $27.5 billion over fiscal year 1990, or a 6.3-percent increase overall.

OVERVIEW

The appropriations request that this committee will consider is $136.8 billion. This is $12.3 billion over fiscal year 1990 or an increase of some 10 percent.

This budget represents not only the President's priorities, but my own as well.

As you are aware, our goals in 1990 that we set were not fully achieved, a prime example being Head Start. That proposal, that program we had proposed with the President's budget an additional $250 million for fiscal year 1990; we ended up with a congressional appropriation of $151 million, some $99 million less than we wanted. But this year we are back to ask for an even greater Head Start appropriation because of our strong commitment to this program, a proposal for $500 million increase in that program which would allow an increase of some 180,000 children in the Head Start Program which would bring us within striking distance of the President's committed goal of bringing all eligible 4-year-olds into a Head Start Program or a Head Start-like program.

We would have some 70 percent of the eligible 4-year-olds in the Nation covered by this program if indeed it is approved, so I certainly solicit your support for addressing this program.

I would also add that at the Governors' meeting with the President in Charlottesville a few months ago, the Head Start Program was uniformly cited by the Governors as a program that works, that is successful, helps meet the goal of having all children in the Nation ready to begin school. The Head Start Programs helps tremendously not only with its educational benefits, but it is health, nutrition, and other benefits as well.

We were also disappointed last year that the funds that we had requested for the human genome project were not fully funded. That program is funded, I believe, at $60 million this year. We have requested an increase of $108 million for this. This represents a major scientific undertaking, one which has been identified by scientists. It is probably the highest priority, major, big science effort that we should undertake.

This will help us map the 3 billion genetic bases in the human chromosomal complex and will give us a handle for greater understanding of the more than 3,500 genetic diseases and, more importantly than that, give us information that we can use to bring forward new therapeutic developments to improve the health of our citizens.

Now, in fiscal year 1991 we are committed to improving the health of the American people, and our program that we have submitted, our budget, will focus on helping children, strengthening families, investing in the future through our biomedical research effort, improving access to health care, promoting good health, fighting AIDS, combating drug abuse and, as you noted, we do have the lead responsibility for the demand reduction activities for drug abuse. That includes treatment, research, prevention activities, and education, and we are fully committed to that.

ENTITLEMENT PROGRAMS

We are also committed to prudently managing the entitlement programs which we are supervised to really hold in trust those for the American people. I speak of, of course, not only our Medicare trust funds, but also our Social Security trust funds as well.

In addition to the Head Start Program that I have already discussed, we are requesting the full authorized ceiling for our JOBS Program; that is $1 billion that we have requested. This program, which was passed by the Congress in 1988, will give individuals on welfare, on AFDC, a real opportunity to develop job skills and educational skills that they can enter the market, become self-sustaining, and this is not only important economically, but it is also important in terms of how our citizens view themselves as directing their lives. We are proud to say that program was implemented with our regulations on time last year. We have some 27 States that have implemented the JOBS Program, and the increase in our budget will help us meet the goal of having all States having implemented JOBS Program by October 1 of this year.

We also are requesting increased support for our AFDC related child care. That will increase by some $283 million for a total of $489 million.

We are also requesting a $47 million increase in child welfare services. This increase would represent a 19-percent increment, and this would help communities manage increasingly more difficult caseloads.

We are proposing in addition a 10-percent limitation on annual increases in foster care administrative costs. This proposed limitation will help to keep these costs in check which have escalated by some 2,800 percent over the last several years, but this will not interfere with the payments to foster families or training of parents and staff.

We are also back to request significant funding for the homeless. We are requesting a total of $233 million, $27 million of which was provided in fiscal year 1990. As you know, the President voiced his commitment in February of last year to full funding of the McKinney Act homeless programs.

On January 24 of this year the President announced his new national drug control strategy. As I mentioned, my Department has the lead responsibility for the demand reduction efforts and in our budget we have requested some $1.7 billion to help us meet our goal of better treatment and better research and prevention and education activities.

We will also have several new initiatives in our drug control strategy including a $50 million community prevention grant program and a $6 million project providing nonmedical services for infants born addicted to crack. We are seeing an increasing problem in our cities with crack babies.

Our budget also includes funds to increase access to quality health care, particularly for disadvantaged pregnant women and their infants. Clearly the fact that our Nation ranks 18th among the industrialized nations in infant mortality is a disgrace. We feel that we should not be No. 1, as you pointed out, Mr. Chairman, in per capita expenditures for health care and 18th in infant mortality. This is a problem. We know what to do. We simply have to focus our resources on doing it. The initiatives in our budget focus $63 million to target programs which address infant mortality. In addition to an overall spending of some $3 billion in different programs that assist in infant care. This improves our outreach activities in a variety of strategies for pregnant women.

We also are pleased that the Medicaid expansions that were enacted as a result of the President's request last year bringing women with incomes up to 133 percent of the poverty levels into the Medicaid Program as well as their children up to age 6 will help significantly to address the health programs of our citizens.

Now, our death rates for our minority populations, as you know, really are significantly higher. This includes not only cancer, but also heart disease, a variety of other disorders as well and because of the fact that the life expectancy of black Americans is some 6 to 8 years less than white Americans as a result of this health gap, we are proposing a special minority initiative of $117 million which includes funds to support more training of minority health professionals, health programs for housing projects in conjunction with housing and urban development and other initiatives there as well.

Concerning rural health care, our budget includes some $357 million to provide access to rural health for our citizens; 92 percent of this amount or $327 million, will be spent on services given in rural communities. This includes the continuation of those activities initiated by the Congress last year for disease prevention and information outreach.

Some $30 million is earmarked for research on the special conditions impeding access to quality care in rural settings. We also plan to spend some $9.4 million to support research by the Alcohol, Drug Abuse, and Mental Health Administration on projects that specifically focus on mental health services in rural areas.

As I indicated previously, we are committed to strengthening our Nation's biomedical research enterprise. Thus, in this fiscal year, we propose to provide a total of $8.9 billion for biomedical and behavioral research at NIH as well as ADMHA. This is an increase of $436 million to strengthen basic research and development efforts of NIH and ADMHA.

Included in this, of course, is the human genome project that I discussed previously. We hope that you will agree with us that it is a high priority that should be funded.

We also include in our budget funds, $89 million for infrastructure improvements on the campus of NIH itself. Over the years we have delayed structural improvements and maintenance, and we can no longer do that, so that we hope that you will support our effort to provide some $89 million for needed improvements in our physical facilities on the NIH campus. NIH is a premier biomedical research institution, which has not only been central to the many achievements we have made in improving the health of our citizens over these last several decades, but also is unequalled around the world as a facility that brings together on one campus a number of outstanding scientists. We have a number of Nobel laureates on that campus, and we want to do everything that we can to preserve and enhance the productivity of NIH, not only for the advancement of knowledge, but also for the advancement of health as well as the importance of its advances to our biotechnology programs.

As you know, biotechnology represents one of the few areas where as a nation we have a very strong positive balance of payments. Biotechnology is in its infancy and represents tremendous potential not only for the advancement of our medical capabilities, but also from an economic perspective, it represents a tremendous opportunity for us to extend our lead in comparison with other nations and will have tremendous economic benefits as well.

So, from all of those perspectives NIH is important, and we hope that you will support our request.

Concerning AIDS we, in fiscal year 1991, for all AIDS including treatment, propose to spend $3.1 billion. Of that $1.7 billion is for activities of the Public Health Service for research, education and prevention activities. In addition, within this amount there is a $780 million increase for Medicare and Medicaid services for AIDS and HIV-infected individuals.

In our budget we also propose to support our new agency for health care policy and research at the level of $110 million. This includes funds for our medical effectiveness research or outcomes research that we commented on last year when we appeared before this committee.

This is an important part of our strategy to improve the quality of care given our citizens as well as to help us contain costs by knowing which treatments we give to our citizens are effective and which are not.

I am committed to ensuring the quality of services provided to the public through our large entitlement programs administered by our department: Social Security, Medicare and Medicaid.

In fiscal year 1991 we are requesting increases for the Social Security Administration and for HCFA which will enable us to continue managing these programs effectively and efficiently. For Social Security we request full funding for our supplemental security income for Social Security and for black lung benefits.

In addition, we are requesting $4.2 billion or an increase of some $330 million for our Social Security Administration to run these programs.

I am pleased to say that our budget proposes to support some 63,000 employees in previous years that Social Security number of employees has declined from 80,000 to 63,000. We have had tremendous improvements in productivity because of automation, and better management practices, but we feel that we now are at a level that we cannot and should not go below that, and our budget stabilizes the number of employees in SSA so that we can continue to provide quality services to our citizens by maintaining the necessary number of employees.

Our budget also proposes to stress managed care or health delivery for our citizens. We are proposing changes to our Medicare Program which will save some $5.5 billion from projected increases in our Medicare budget.

These changes are designed to make our Medicare Program a prudent purchaser of services and to assure that current inequities in physician payments are not built into the new reimbursement system to be implemented in fiscal year 1991. With our proposals Medicare expenditures will increase by some 4.6 percent over fiscal year 1990. Without these restraints on our growth in spending, we would be facing a 9.9-percent rate of increase in our Medicare expenditures and such a rate is not sustainable.

Also in our budget you will note that we propose to finance some of the services by user fees. For example, we request approval for $510 million or an increase of $312 million over our 1990 budget for survey and certification of health facilities to ensure the safety and quality of care provided with our Medicare and Medicaid funds. Following the lead of the Congress in the Clinical Laboratory Amends of 1988, we propose funding all activities including those previously funded by Medicaid through user fees.

PREPARED STATEMENT

Finally, Mr. Chairman, our budget honors the 1983 bipartisan agreement on Social Security to ensure that we have a sound program, not only to provide benefits for today's citizens, but also for those of our children and our grandchildren. We urge you not to contemplate any sort of action which will ultimately endanger the economic future of our citizens today and tomorrow. That completes my statement. I will be pleased to respond to your questions.

[The statement follows:]

STATEMENT OF DR. LOUIS W. SULLIVAN

Mr. Chairman and Members of the Committee, thank you for inviting me here today to discuss the President's fiscal year 1991 budget proposal for the Department of Health and Human Services. We are requesting $464 billion in outlays, an increase of $27.5 billion over current year spending.

Our appropriation request for HHS programs considered by this Committee totals $136.8 billion. This is $12.3 billion over fiscal year 1990, or an increase of almost 10 percent.

This budget reflects the President's and my own priorities for the Department. I am proud of this budget and look forward to working with the Congress for its enactment.

As you and I are aware, several of our goals for 1990 were not fully achieved, a prime example being the expansion of Head Start. This year, we are seeking an unprecedented increase of $500 million for the program, which will open new doors of opportunity to an additional 180,000 children and their parents. I want you to know that I share President Bush's enthusiasm for this expansion. In the spirit of cooperation, we must work together to get every dollar of this increase.

We were also disappointed that, last year, funds we received for the homeless, the Human Genome Project and AIDS were less than requested. In each of these areas, I am back this year asking for more, and I hope that, together, we can bring about these increases.

For fiscal year 1991, the Department's efforts to improve the health and well-being of the American people will emphasize my major goals -- helping children and strengthening families, investing in the future through enhanced biomedical research, improving access to health care, promoting good health, fighting AIDS, combating drug abuse, prudently managing our large entitlement programs and increasing the quality of services provided to the public.

Let me take this chance to go over some of the highlights of my request:

For the Head Start program, we are asking for a 36 percent increase, bringing the total for Head Start to $1.9 billion. The expansion of Head Start is a key ingredient in assuring that all our children start school ready to learn, one of our national education goals. The addition of $500 million will allow 180,000 additional children to receive the learning, skills and confidence Head Start offers. I hope that Congress shares this goal and will support this critical increase. Every eligible disadvantaged 4 year old deserves the opportunity to enjoy a Head Start experience.

As part of our expanded support for families in need, we are requesting the full authorized ceiling of $1 billion for the new Job Opportunities and Basic Skills Training Program. The education, training and work activities provided under the JOBS program are essential for restoring dignity to families on AFDC and readying them for the employment opportunities this decade will bring. Our request will enable the 23 states without JOBS programs to implement them, as required, by October 1990.

To provide additional assistance for parents entering the workplace, support for JOBS and AFDC-related child care will increase by $283 million for a total of $489 million. Increased availability of child care services will allow more AFDC parents the opportunity to complete education, training and work programs successfully, and move themselves and their families permanently off welfare and out of poverty.

To bring about much needed reforms in the areas of child welfare and foster care, we are requesting a $47 million increase for Child Welfare Services. This 19 percent increase will help communities to manage increasing and more difficult caseloads. Additionally, we are proposing a 10 percent limitation on annual increases in Foster Care administrative costs. This limitation will keep these costs in check, but will not interfere with payments to foster families or training of parents and staff.

Again this year, the President and I are making good our promise to help America's homeless. We are requesting $233 million, $27 million of which was provided in fiscal year 1990. Last year, the Congress was unwilling to meet our request in this area. This year, we hope HHS health care and community service programs targeted at our homeless population will be funded at the levels of our request.

On January 24, in announcing his new National Drug Control Strategy, the President renewed his commitment toward demand reduction efforts. To address this and other HHS anti-drug abuse activities, we have included $1.7 billion in our request. This level of funding will allow increases in almost all aspects of this Department's efforts to win the war on drugs. It will also provide for new initiatives, including a $50 million community prevention grant program and a $6 million project providing non-medical services for infants born addicted to crack. The American public is demanding much more action in preventing and treating drug abuse, and we are responding to this call for help.

As a part of this budget, our efforts for increasing access to quality health care will focus on disadvantaged pregnant women and their infants. Clearly, the fact that the United States ranks near the bottom of all industrialized Nations in infant mortality is disgraceful. To concentrate on improvement in this area, our budget includes an increase of $63 million for PHS programs aimed at reducing adverse pregnancy outcomes and improving infant survival. It also fully funds the enacted Medicaid expansions for pregnant women and their children with incomes at or below 133 percent of poverty.

Death rates among minorities for heart disease, cancer, stroke, AIDS and other disorders are far greater than those of the population as a whole. Correcting the disparity in health status between minority and non-minority populations remains one of my highest priorities. To this end, we are seeking $117 million for a new initiative to improve access to health care for low-income minorities. This will include increasing the number of minority health professionals and initiating innovative community-based approaches to recruiting minorities into health careers. We will also develop new strategies for delivering needed health services to our minority populations.

In addition, the budget includes $357 million for access to care for rural Americans. Ninety-two percent of this amount, or $327 million, will be spent on services for rural communities. This includes continuation of those activities initiated by Congress last year for disease prevention and information outreach. $30 million is earmarked for research on the special conditions impeding access to quality care in rural settings. We also plan to spend $9.4 million to support ADAMHA research projects and services which specifically focus on mental health services in rural areas.

The future challenges of this decade demand continued advancement of our Nation's research enterprise. In fiscal year 1991, we will provide a total of $8.9 billion for biomedical and behavioral research. Our $436 million increase will strengthen the basic research and development efforts of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration.

Included in this increase is a major expansion for the Human Genome Project. This research is expected to have a profound effect on our ability to treat the more than 3,500 diseases of known genetic origin. The project was recently ranked by researchers as the number one Federally-funded major science initiative, surpassing even the Super Collider. It must remain one of our highest priorities. We are planning an increase of $48 million over the $60 million Congress provided in fiscal year 1990.

To begin the much-needed infrastructure repair of the NIH campus, I am requesting $89 million. We can no longer continue to ignore the fundamental needs of our researchers; facilities must be well maintained and renovations must occur.

Concerning AIDS, we must work until our efforts match the threat of this disease to our society. In fiscal year 1991, we propose to spend $3.1 billion on AIDS. We are requesting $1.7 billion for HIV and AIDS-related activities of the Public Health Service. This $109 million increase will be used for continued research, education, epidemiology and investigation of drugs. In addition, there is a $780 million increase for Medicare and Medicaid services for AIDS and HIV infected individuals.

$110 million is also included for the newly established Agency for Health Care Policy and Research. This amount includes funds for an expanded Medical Treatment Effectiveness Program. The Effectiveness program is a comprehensive effort to learn which medical procedures are most effective for specific health conditions. Effectiveness research is a long-term commitment toward improving the quality of medical care and reducing unnecessary treatments.

I am committed to ensuring the quality of service provided to the public through the large entitlement programs administered by this Department -- Social Security, Medicare and Medicaid. In fiscal year 1991, we are requesting increases for the Social Security Administration and the Health Care Financing Administration which will enable us to continue managing these programs efficiently and effectively.

The budget includes full funding for Social Security, Supplemental Security Income and Black Lung benefits. In addition, we are requesting $4.2 billion, an increase of $330 million, for the Social Security Administration to run these programs. These funds will allow SSA to stabilize staffing at about 63,000 and continue to invest in automation, thus ensuring high quality service to our public.

Our legislative agenda includes several initiatives which will encourage the provision of health services in managed care settings. We believe managed care is the best means of assuring quality service and appropriate care for Medicare and Medicaid beneficiaries.

We are also proposing changes to the Medicare program which will save $5.5 billion. These changes are designed to make the Medicare program a prudent purchaser of services and to assure that current inequities in physician payments are not built into the new reimbursement system to be implemented in fiscal year 1991. With these proposals, Medicare expenditures will increase by 4.6 percent between fiscal year 1990 and fiscal year 1991. Without them, the inflation rate of this program would continue at more than double that rate, or at 9.9 percent.

You will note that in our budget, we are proposing to finance some of the services we provide through user fees. For example, my request includes $510 million, an increase of

$312 million over the 1990 level, for survey and certification of health facilities to ensure the safety and quality of care provided. Following the lead of the Congress in the Clinical Laboratory Improvement Amendments of 1988, we propose funding all activities, including those previously funded by Medicaid, through user fees.

Lastly, and perhaps most importantly, our budget honors the 1983 bipartisan promise to Americans that there will be sufficient funds for social security today and in the future. Further, we propose additional protection for future beneficiaries through a plan which would end the current practice of using reserves to mask the size of our deficit. Let's not contemplate any sort of action which will ultimately endanger the economic future of our children and our grandchildren.

Thank you very much. I will now be happy to answer any questions you have about our request.

BIOGRAPHY OF DR. LOUIS W. SULLIVAN

Louis W. Sullivan, M.D., was sworn in as secretary of health and human services March 10, 1989, by U.S. Circuit Judge A. Leon Higginbotham Jr. He was nominated by President Bush Jan 20, 1989, and confirmed by the Senate March 1, 1989

As head of the Department of Health and Human Services, Dr. Sullivan oversees the federal agency responsible for the major health, welfare, food and drug safety, medical research and income security programs serving the American people.

Dr. Sullivan came to HHS from the Morehouse School of Medicine in Atlanta, Ga. In July 1975, Dr. Sullivan had become founding dean and director of the medical education program at Morehouse College. Since July 1, 1981, when the School of Medicine became independent from Morehouse College, he had served as its first dean and president. In April 1985, the Morehouse School of Medicine was fully accredited and on May 17, 1985, the school awarded the M.D. degree to its first 16 graduates.

Dr. Sullivan was born in Atlanta Nov. 3, 1933. He received a bachelor of science degree, magna cum laude, from Morehouse College, 1954; and earned his medical degree, cum laude, from Boston University, 1958. He did his internship (1958-1959) and medical residency (1959-1960) at New York Hospital's Cornell Medical Center. After a pathology fellowship at Massachusetts General Hospital (1960-1961), Dr. Sullivan became a fellow in hematology at the Thorndike Research Laboratories of Harvard Medical School at the Boston City Hospital.

He was an instructor in medicine, Harvard Medical School, 1963-1964, and an assistant professor of medicine, New Jersey College of Medicine, 1964-1966.

In 1966, he became co-director of hematology at Boston University Medical Center. From 1966 to 1975, he was, successively, assistant professor of medicine, associate professor of medicine and professor of medicine at Boston University School of Medicine. During 1972-1975, he also was co-project director and project director of the Boston Sickle Cell Center and director of Hematology at Boston City Hospital.

Dr. Sullivan returned to Morehouse, his alma mater, in 1975 as professor of biology and medicine.

He is a member of the American Medical Association, the National Medical Association, Atlanta Medical Association, Medical Association of Atlanta, Medical Association of Georgia and the Georgia State Medical Association. He has been certified in internal medicine and in hematology. His research interests are in hematology.

Dr. Sullivan was the founding president of the Association of Minority Health Professional Schools. He is a former member of the Joint Committee on Health Policy of the Association of American Universities and the National Association of Land Grant Colleges and Universities.

Professional honors received by Dr. Sullivan include election to Alpha Omega Alpha Honor Medical Society in 1957, election to the American Society of Clinical Investigation in 1970, to Phi Beta Kappa in 1974, to the Institute of Medicine (National Academy of Sciences) in 1975 and to fellowship in the American College of Physicians in 1980. From 1985 to 1987 he was vice chairman of the Commission on Health and Human Services of the Southern Regional Education Board.

He served as associate editor of Nutrition Reports International, 1969-1973; on the Editorial Board of the American Journal of Hematology, 1975-1977; and on the Editorial Board of the Journal of Medical Education, 1977-1978. He has served as consultant and adviser to numerous organizations and agencies including several in HHS' Public Health Service and for the Veterans Administration. Prior to becoming Secretary, Dr. Sullivan was a member of the National Cancer Advisory Board of the National Cancer Institute, National Institutes of Health. He is a member of the boards of Friends of the National Library of Medicine and the Boy Scouts of America. He has been a member of the Atlanta Rotary Club since 1977.

Other honors received by Dr. Sullivan include: Boston University Alumni Award for Distinguished Public Service in 1965; Honoree of the Year of the State Committee on the Life and Health of Black Georgians in 1983; the Drum Major Award by the Southern Leadership Conference in 1982; establishment of the annual lectureship at the Morehouse School of Medicine in his honor in 1980; the Outstanding Alumnus Award from New York University's Cornell Medical Center in 1984; honoree of the National Association of Minority Medical Educators (NAMME) for outstanding contributions to the education of minorities in medicine in 1984; the first Martin Luther King Visiting Professorship at the University of Michigan in 1986; the Equitable Southeastern Regional Black Achievement Award for Education in 1986; and the Atlanta Urban League Award for Outstanding Community Leadership in 1987. He was a member of then-Vice President George Bush's official 12-member delegation to seven African countries in mid-November, 1982.

Dr. Sullivan and his wife, Ginger, have three children.

HEALTH CARE COSTS

Senator HARKIN. Thank you for a very good, comprehensive, and straightforward statement. I appreciate it very much.

If I might cover a couple of general questions before I get into specifics. Mr. Secretary, in the State of the Union Message President Bush directed you to undertake a major study of health issues in the next few months. The Pepper/Rockefeller Commission will also be reporting on its recommendations.

The congressional debate is going to intensify over issues of long-term care, coverage of the uninsured, and soaring medical costs. It is the issue of soaring medical costs that I would like to discuss right now.

Skyrocketing national health costs are expected to reach $661 billion in 1990, close to 12 percent of our gross national product, twice the proportion of 1965 and the highest proportion for any developed nation.

We spend far more on health care per capita than our major industrial competitors throughout the world, which puts us at a grave disadvantage. It aggravates our efforts to control the deficit, it plays havoc with personal finances, especially for the elderly.

I guess my question, Mr. Secretary, is one of broad, very broad policy. Why is our health care system so expensive? What, in a broad context, can we do to bring it under control?

Secretary **Sullivan**. Mr. Chairman, there are a number of reasons. First of all, there is no challenging the position that at its best the American health care system has no equal in terms of the power, technology, training of our health professionals and the variety of services that we can provide.

We can do a number of things now which were virtually unheard of when I was a medical student. Kidney transplants were just being tried when I was in medical school. Not only are we now doing kidney transplants, but heart transplants, bone marrow transplants, liver transplants, et cetera.

While we have emphasized our high technology with spectacular results; we have developed a system that is very expensive. We have also neglected primary care, the fundamental bedrock of our system. We now have a system that is skewed.

We need to work very diligently to change the health behavior of our citizens. If you look at the major causes of death and disability in our population, they are conditions in which the behavior of the individual plays a major role. Our No. 1 killer is heart disease. That clearly is influenced by diet, exercise, smoking and other activities. High blood pressure and stroke also contribute.

SMOKING

The second major cause of death is cancer. The No. 1 type of cancer is lung cancer, which is directly a result of smoking. We have seen some success with the decline of smoking in white males in our society, and that decline in smoking is also now being followed by a decline in the rate of lung cancer in that population. However, white females have increased their smoking over the past 25 years and we now are seeing an increase in lung cancer in them. In 1985 lung cancer in women exceeded breast cancer as the No. 1 cause of cancer in women.

Senator **Harkin**. When did that start?

Secretary **Sullivan**. Starting in 1985 lung cancer has beeen No. 1 in white females, and that clearly is related to smoking.

In December 1988 when President Bush nominated me to this position I indicated that one of my top priorities would be health promotion/disease prevention.

My reason is, we are not going to reach our goal of improving the health status of our citizens while controlling costs, if we do not have their active participation by changing their health behavior. We obviously also have problems with drug abuse that are destroying the future leadership in our society. Problems with AIDS also clearly related to personal behavior.

To make a short answer to your question, we need work at the Federal and State level to restrain costs; and we need to have the participation of our citizens. We have relied too much on a medical model for our health care system; that is, treating conditions when they have risen. We need to move more toward prevention. It is this combination of working with our citizens, businesses, educational system and with our Federal and local governments that we are going to improve the health of our citizens and restrain costs.

Senator HARKIN. Do you have any estimate on how much we spend in this country every year on health care as a result of smoking, like lung cancer and things like that? How much a year do we spend?

I heard a figure. I just wondered what——

Secretary SULLIVAN. Our Office on Smoking and Health has that data, and perhaps we might supply that for you.

[The information follows:]

SMOKING-RELATED HEALTH COSTS

The total societal economic impact of smoking in the United States is more than $52 billion annually. This averages to an annual per capita cost of smoking-related diseases of $221 nationally, ranging from a low of $56 per person each year in Utah to $284 in Rhode Island. Of this total $52 billion adverse economic impact, approximately $23.7 million, or 45.2 percent, is estimated to be due to direct health care costs of smoking-related illnesses.

SMOKING-RELATED COSTS

Senator HARKIN. I heard a figure around $60 billion, but I do not know if that is correct. It was somewhere around that, and I guess the question I have is I do not smoke, nor does anyone in my family smoke. Why should I have to pay for those people who decided to smoke all their lives and who now have to have all this high-cost medical care for lung cancer?

Senator BUMPERS. The rest of us do not drink and you do. That's the difference between us. [Laughter.]

Secretary SULLIVAN. I am glad you raised that.

Senator HARKIN. I do not mind him raising it. I do not know if I care for the way he raised it. [Laughter.]

Secretary SULLIVAN. Indeed, we have a number of problems that clearly are related to behavior. For example, as you know, we have had raging battles about whether people should use seat belts. Some people cite this as a first amendment privilege—not to use seat belts.

The fact is when people are killed in automobile accidents, we are deprived of their contributions to society, and we pay for uncompensated care that we provide.

Senator HARKIN. I am just wondering if you would be interested in making a recommendation that those who chose to smoke perhaps a dedicated increase of taxes on cigarettes that would go into a trust fund to pay for the care of those people that get lung cancer. If they want to smoke, let them pay for the health care that comes with it.

Secretary SULLIVAN. Mr. Chairman, we have a number of things under development within the Department on the problem of smoking and other health issues. We will be pleased to work with you on these.

Senator HARKIN. I also mentioned earlier—again, a broad policy question. Canada to the north, again, they are not that much different than us. They pay one-third less for health care per capita. As I mentioned, they had 37 malpractice suits last year; 37. That is all in the entire country.

Are there any lessons that we can learn from Canada? Is there anything there that we can learn about health care delivery, and the efficiency of our own health care system?

Secretary **SULLIVAN**. Certainly I think that there are some important lessons that we can learn from the Canadian experience. While there are some victories that the Canadian system has, there are also some real problems too.

The Canadian system has in many instances lines or other delays in some elective procedures.

Senator **HARKIN**. But in elective procedures. You said elective procedures?

Secretary **SULLIVAN**. Yes.

Senator **HARKIN**. But how about for primary care?

PRIMARY CARE

Secretary **SULLIVAN**. There have been significant improvements that the Canadians have developed, and for that reason we have placed greater emphasis on primary care in this budget. We proposed to reimburse hospitals for primary care residency training at a higher rate than residency training in other areas.

In physician payment reform that the Congress passed last year, a feature provides bonus payments to primary care physicians in rural and inner city areas as well. So, indeed, we are undertaking a number of efforts to emphasize to a greater extent training more primary health practitioners, better reimbursements, and restraint in fees for many of the specialties. We don't need to have additional specialists.

Senator **HARKIN**. Thank you, Mr. Secretary.

I recognize my colleague, Senator Specter.

Senator **SPECTER**. Thank you, Mr. Chairman.

Mr. Secretary, you have identified in your opening statement your Department's lead responsibility, as you categorize it, for treatment, research, education, the panorama on the demand side, on the drug problem.

Director Bennett testified before the Judiciary Committee on Friday saying that he thought that education was not as important as enforcement and prosecution, and that was the lead story on the front page of the New York Times on Saturday, and I was among a number of members of the Judiciary Committee who disagreed with Dr. Bennett on that subject.

I believe that the supply side is very important, have authored legislation for career criminals and the jail aspect, but it seems to me that we ought to have equal emphasis on supply and on demand in this country and that we ought not to elevate prosecution over education rehabilitation.

I think we have to emphasize the prosecution and the jailing and law enforcement. It is professional work I have done for many years, but I think we have to give equal emphasis to education and the demand side.

Now, I do not necessarily want to start a controversy between you and Dr. Bennett on this subject, but I do believe that it is necessary that there be a forceful statement made on the demand side by the man, if that is your view, person in charge with lead responsibility.

And my question to you is do you think that education ought to take a back seat or be secondary to law enforcement and the supply side?

DRUG REDUCTION

Secretary SULLIVAN. The Department does have the lead responsibility for demand reduction activities. We have been proud of the fact that under the President's proposed drug strategy between 1989 and 1991 in our budget we have actually doubled from about $500 million to slightly more than $1 billion, moneys for treatment and programs.

Senator SPECTER. You say $500 million to $1 billion?

Secretary SULLIVAN. Yes; for treatment alone.

We have also established an office for drug treatment research just during this past year. That is out of the Alcohol, Drug Abuse, and Mental Health Administration. We were pleased about 2 months ago to appoint to head that office Dr. Frederick K. Goodwin, a nationally recognized expert on drug treatment programs.

We also have about $500 million for prevention and education programs in our budget. We have a total of $1.7 billion overall for our demand reduction activities, or roughly 29 percent of the President's proposed funding for our overall drug strategy.

Now, concerning the statement that Dr. Bennett made, I have not had a chance to talk directly with him, but read that statement, I believe he said that if he were forced to make only one choice, he would choose enforcement, but that he felt that education was an important part of that.

Let me emphasize unequivocally that an education program must be an integral, very significant, important part of any effort to control the drug epidemic in our society.

Senator SPECTER. You say integral, very important. Equal?

Secretary SULLIVAN. Absolutely.

Senator SPECTER. Not second to?

Secretary SULLIVAN. We are never going to combat drug abuse in our society without a strong educational effort.

Senator SPECTER. Dr. Sullivan, when you talk about $1.7 billion and 29 percent, why not 50 percent?

Secretary SULLIVAN. We are concerned with the funding for our programs, but also training of personnel to staff treatment facilities. That is a major challenge because appropriating the money does not mean that the next day our programs are doubled. We need time to train drug counselors.

Senator SPECTER. The same thing applies to enforcement, but in terms of a total goal, why should it not be 50 percent?

Secretary SULLIVAN. The overall distribution of the President's drug program is about one-third for foreign initiatives in terms of interdiction. About one-third is for local law enforcement within the United States, and then the other one-third is for our own efforts.

Senator **Specter**. The problem with that may be that if you have got one-third, one-third, and one-third, you have got two-thirds on the supply side and you have got a lot of money on the Department of Defense which does not come out of the drug budget, which is really on interdiction, and if you have a third for supply side—for demand, that is a lot more than 29 percent. You take 4 percent of $10.6 billion, that is a lot of money. It is a lot of money without doing the math.

I do not want to pursue it beyond this point.

Your statement that you think the demand side ought to be equal is a good starting point, but I would just urge that we maintain equity between funds on the supply side and the demand side.

Secretary **Sullivan**. If I could follow up, Senator, we were pleased to announce the results of a 1989 senior high school survey of drug use. That survey showed between 1985 and 1988 there was a dramatic fall, roughly 33 percent, in casual drug use among high school seniors, from around 37 million individuals who had used drugs within the past month down to 24 million. That was the first real evidence of the results of our educational effort. We are hopeful that we will be seeing a continuing fall.

Now, the problem that we saw in that report was that the hardcore users, the addicts, increased by some 25 percent. So in that part of the drug war toward casual users, we see turning of the corner, because casual users eventually will turn into the hardcore users.

We certainly need to continue and increase our efforts with the hardcore users because that is the group using crack, is associated with violence in our inner cities. Clearly we have a lot to do there.

From the standpoint of the casual users we believe that our educational efforts are working and by all means should be continued because we have not won the war yet. We see some progress being made in some areas, but problems in other areas. We are never going to conquer the problem of drugs in our society without a strong educational effort involving all of our citizens.

Senator **Specter**. Let me just ask you one more question at this point before yielding to my colleagues because these are complex matters, and they require a fair amount of response and understandably so. I do not want to keep my colleagues waiting, and I want to come back for a second round.

Will we have that, Mr. Chairman?

Senator **Harkin**. Yes.

Senator **Specter**. But I want to turn now to a subject that I raised with you last year, and the thrust of my concern is why does it take so long, in the administration process to finally get awarded program funds appropriated by this subcommittee?

DRUG PROGRAM ADMINISTRATION

Last year when you came to testify on April 10, I raised an issue with you about a program which I had visited just that day in Philadelphia for the homeless. I said, at that time, that I was surprised to see relatively young men in their twenties, thirties, and early forties that appeared to be able bodied, but they were drug users, alcohol users and the necessity arose to get them detoxification. They also were homeless, and thus, shelter would be necessary in order to start them on job training programs, a subject we discussed yesterday with Secretary Dole.

I made the comment after you had responded that I wanted to start early to make the presentation to you on a Philadelphia pilot project, and it has been very frustrating to see the months go by, and it was not until January 26, just a few days ago, there was a request for application issued by the Department of Health and Human Services, under a cooperative agreement for a research demonstration project on alcohol and other drug abuse treatment for homeless persons.

And my concern, Mr. Secretary, and I understand the problems that you have, but if the matter is elevated to an exchange between the ranking member of the subcommittee and the secretary, and it takes from April 10 until January 26 to get a letter out for step one, what are we to do in coming to grips with this terrible problem if it takes this long to do that? And that is the overarching question.

The subordinate question is when are we going to get this project for Philadelphia, but the overarching question is how do we function if when it comes up in this context between you and me and this time interval lapses?

Secretary SULLIVAN. Senator Specter, I think there are a number of issues that are involved in that. I, too, feel the same sense of frustration that it takes so long. But as you know, we do have a very strong commitment to addressing the problems of homelessness, alcoholism, and drug abuse in our society.

In fact, I had the pleasure on two separate occasions to visit facilities in Philadelphia that were addressing the homeless. One was a facility that had come into being as a result of our regional director in the Philadelphia office, who obtained from the Department of Defense through the General Services Administration a facility that had been renovated to serve as a training center and dormitory for homeless alcoholic men. It gave them job training, and this particular facility in south Philadelphia, I think, has thus far had an exemplary record of detoxification of these men. Working with local businesses, they graduate from the program with a job and move out into the community.

That particular program, also, was considering establishing a second such facility in another part of Philadelphia for homeless women as well. Clearly that program seems to be one that is working.

The second visit was to a house that had been established for mentally ill homeless individuals in Philadelphia. That house was being run by the mentally ill homeless individuals themselves. We clearly have an interest in a commitment to that.

As you may be aware, I serve as vice chairman of our interagency task force on homelessness that Secretary Kemp chairs.

Some of the reasons that it takes so long are as follows. First of all, as you know, the appropriations for the current year were only completed late last year, and the time that——

Senator SPECTER. We are not talking about appropriations. We are talking about an application. I want to follow up with you to get the specifics on people being detoxified and finding jobs and having a success rate because frankly that would surprise me if those results are in hand.

But before pursuing that further, let me get the specifics from you as to those two projects. We are not talking about appropriations. We are talking about just getting an application filed, which they cannot do in Philadelphia until they get this response from your Department.

Secretary SULLIVAN. I will be happy to review that specific situation and get back to you with the details because I agree with your concern and we want to do everything we can to move things as rapidly as possible.

[The information follows:]

PROGRAMS FOR HOMELESS

I am aware of the excellent programs in Philadelphia for the homeless. My staff and I have been in contact with your office and the Mayor of Philadelphia, Wilson Goode, to discuss future homeless projects in Philadelphia.

On July 27, 1989, ADAMHA and NIAAA staff met with staff from Goode's office and Maureen Byrnes of your office in response to funding demonstration projects on homeless persons with alcohol and drug problems. At this meeting, we presented Mayor Goode's staff with materials on the two existing demonstration projects in Philadelphia. These two projects are approximately 28 percent of the total funds available at that time. At this time, Department staff also provided technical assistance on developing grant applications.

On September 6, 1989, I wrote a letter to Mayor Goode providing an update on the procedure for additional demonstration grants. In this letter I stated that the Request for Application (REA) would be forwarded to Mayor Goode as soon as it was available.

The process for soliciting, reviewing and making grant awards is designed to expedite the funding of projects for homeless persons and ensure that those programs are of the highest quality. The following is the timetable the Department anticipates following in order to accomplish both of these goals:

—November, 1989: Appropriation;
—January, 1990: Request for Application (RFA) issued;
—April, 1990: Applications due;
—June, 1990: Applications reviewed by independent outside review group and rated on scientific and technical merit;
—September, 1990: Review by National Advisory Council on Alcohol Abuse and Alcoholism;
—September, 1990: Grant awards made.

Senator SPECTER. I really do not think it is an answer to cite other activities which you have undertaken because they are important, and I will review those. As I say, I would be pleased, as well as surprised, if they are as successful as you have indicated.

But in terms of getting a matter on track which you and I have discussed, I want to see what has happened here and how we get it on track. And I have expressed my concern as to the fact that it may be an indicator as to the heavy redtape in the Department generally.

I will return to more questions because I do not want to take up any more time while colleagues are waiting.

Senator HARKIN. Thank you.

Senator Burdick.

Senator BURDICK. Mr. Secretary, for the first time in many years the President's budget proposal contains significant funding for the

National Health Service Corps program. However, the budget also eliminates most of the funding for the health professions program.

HEALTH PROFESSIONS PROGRAMS

Last week I met with hospital administrators from North Dakota who face a significant nursing shortage. I am also told that we have a shortage of mental health care providers throughout the State. North Dakota health professions programs are heavily dependent on Federal funds because of the State's severe economic problems.

In light of these shortages how can we severely cut health programs in the 1991 budget?

Secretary SULLIVAN. Thank you, Senator Burdick. There are a number of things that we are doing to address this problem. While we have indeed reduced the funding overall for health professions programs, the funds that we have in our budget which I believe are around $76 million are focusing on training primary care health professionals as well as addressing the problem of nursing shortage.

The Nursing Commission submitted its report to my office in December 1988. I appointed a committee headed up by Dr. Marie Henry, who is the senior public health official in charge of nursing programs to address and implement a number of the recommendations included in the report.

Some of the recommendations pertained to increasing the professionalism of nursing, improving working conditions, reducing nonnursing responsibilities, seeing that nurses were represented at a high level in the hospital administrative structure, and addressing the problem of salaries for nurses.

We are working diligently to implement these recommendations of the Nursing Commission's report, and I am confident that we will see some positive results.

One other thing regarding rural health, our budget includes an increase in National Health Service Corps funding of $63.9 million for scholarships and loans to individuals who will be targeted for both rural areas and inner cities.

Senator BURDICK. Mr. Secretary, we will look at this next year when you come up and see what progress has been made.

Some officials in my home State have encouraged me to oppose Medicare expansion. They say they cannot afford to pay for more services given their current budget restraints.

Would you tell the committee what you think of the Oregon Medicaid initiative or similar proposals that give the States the flexibility to prioritize certain Medicaid services.

Secretary SULLIVAN. Senator Burdick, we are following the Oregon program with great interest to see how that works. This is an effort to tackle a very difficult problem, and that is given limited resources, how the dollars are best spent. We are watching Oregon to see if this is, first of all, accepted by their citizens; that is, to provide the limited dollars for more primary care, including immunizations as well as not providing funds for transplantation. That represents a very serious issue that involves a number of ethical and other considerations.

We cannot comment beyond that other than to say we are very much aware of it, and we are following it with great interest.

Senator **Burdick**. I understand the administration's budget for the National Health Service Corps would cover assistance for 750 students. Do you know how many underserved areas currently have vacancies and if it is significantly more than 750, why the administration is not giving this program higher priority? 750 seems very, very small to me.

Secretary **Sullivan**. Senator Burdick, we agree that there are a number of health priorities that we are trying to address. While we may not have an optimal response to this, is we have turned this issue around, and we do have increased funding for this year.

With the budget we propose for fiscal 1991, we would be increasing the total field strength to around 2,200. We are encouraging the use of other health professionals such as nurse practitioners and physicians' assistants as part of the overall health care team.

Nurse midwives can also provide very valuable services in a number of instances.

Senator **Burdick**. Agricultural safety is a top concern in North Dakota and other rural States. Last year Congress included report language instructing the Office of Rural Health to focus on agricultural and safety health issues. Do you know if this effort is underway and if so, how is the effort being coordinated with the USDA?

Secretary **Sullivan**. Yes, Senator Burdick. Through the Centers for Disease Control we are devoting $12.3 million for farm safety because that is an important part of maintaining the health for rural citizens.

LOW-INCOME HOME ENERGY ASSISTANCE

Senator **Burdick**. I am very concerned about the administration's proposal to cut the low-income home energy assistance program, better known as LIHEAP by nearly 25 percent next year.

I receive a great many letters, mainly from senior citizens, about the importance of LIHEAP and the difference it has made in their lives. Where the winter temperatures can be 20 or 30° below zero—that is real temperature—not a wind chill, LIHEAP can literally mean the difference between life and death. I assure you that North Dakotans cannot afford any cuts in LIHEAP. It should be increased at least enough to cover inflation. Instead you are here suggesting that we cut it by nearly one-fourth. Why?

Secretary **Sullivan**. Senator Burdick, this program was first implemented, during the oil shortage—during the years of the oil embargo—and that no longer exists. This was intended from the beginning to be a temporary program during that critical period.

Second, this is a program in which there are widely differing needs in different States and because of that, we feel that it is a program that should be focused more in the States—the demand is so uneven.

This was never intended to be a permanent program of the Federal Government; it was enacted during the time of the oil embargo.

While the month of December was a cold month throughout the Nation and oil prices went up, the fact is now the oil prices as of a few days ago were actually lower than on December 1. Those news stories that all of us saw in December no longer apply.

Senator BURDICK. I do not think you ever lived up there in the Northern States, have you?

Secretary SULLIVAN. No, but I have experienced 59° below zero with the wind chill, so I understand.

Senator BURDICK. Mr. Secretary, the administration again proposes to terminate the community services block grant program which received $389 million in the fiscal 1990 appropriation. As you know, these grants are made to States for community action agencies to run programs providing basic survival services to persons in need.

The plan, as you know, is to replace this nearly $390 million program with a single appropriation of $42 million in funds from the McKinney Homeless Assistance Program. Clearly we must fund programs to help the homeless, and I support this wholeheartedly. However, we must not pit one assistance program against another. We need all of them. We must not cut any of them. In seeking to cut out the funding for community service block grants the President is asking us to terminate the funding for the agencies that run 35 percent of the Head Start Programs for which he expresses such an affection.

I also found in your budget justification statement a suggestion that the assistance currently provided by community service block grants could be replaced by some other programs. One program which was mentioned was LIHEAP, the low-income home energy assistance program. Yet the same budget plans to cut one-fourth of LIHEAP's funds. Why does the administration repeatedly seek to terminate CSBG funds, knowing that the public wants this program and Congress wants it?

Secretary SULLIVAN. We believe that the purposes of the block grant program are being served in other areas of the budget, in LIHEAP, and the JOBS Program.

As I mentioned in my testimony, we are proposing full funding, at $1 billion, for the JOBS Program. This represents a significant funding increase and also the increase in our Head Start Program of $500 million that will help. Other Federal agencies, including the Small Business Administration, also help to address those needs as well.

Whereas we propose to eliminate these programs from the community services block grant, they are being served in other areas of our Department, as well as in other Departments. Some of our programs such as the JOBS, which I think was $463 million last year goes to $1 billion in our budget, and the Head Start Program goes from $1,386 million to $1,886 million.

Senator BURDICK. Thank you very much.

Senator HARKIN. Thank you. Senator Bumpers.

Senator BUMPERS. Thank you, Mr. Chairman.

Dr. Sullivan, welcome to—I guess your first appearance before this subcommittee.

Secretary SULLIVAN. Second.

Senator BUMPERS. I missed the first one.

Dr. Sullivan, who is Acting Director at NIH?

NIH DIRECTOR

Secretary **Sullivan**. It is Dr. William Raub who is the Acting Director.

Senator **Bumpers**. Are you on the committee to select the successor to Dr. Wyngaarden?

Secretary **Sullivan**. I am not on the search committee which I appointed, and will be making their recommendations to me.

Senator **Bumpers**. Have you prescribed a litmus test that the new Director will have to pass, for example, on the abortion issue?

Secretary **Sullivan**. No; Senator Bumpers, I did not. The search committee has a number of distinguished people from the private sector: Harold Amos, Ph.D., Harvard Medical School; Theodore Cooper, M.D., Upjohn Co.; James F. Dickson III, M.D., Boston University; James R. Gavin III, M.D., University of Oklahoma; Frederick C. Robbins, M.D., Case Western University; Richard S. Ross, M.D., Johns Hopkins University; Virginia V. Weldon, M.D., Monsanto Co., and others. I indicated to them that the primary criteria for the new director at NIH would be scientific excellence and administrative capabilities.

I further indicated to them that I had discussed this matter with the President and his chief of staff, and they support me in that position. I also made a public address on that issue in November of last year to the Association of American Medical Colleges where I related to them the fact that it was unfortunate that a low level individual in the White House personnel office, without my knowledge or concurrence, had made such an inquiry concerning abortion to an individual whose name had been submitted.

Senator **Bumpers**. A person I would like to have seen head up NIH.

Secretary **Sullivan**. We had not submitted any names to the White House at that time.

Senator **Bumpers**. You are sure that a litmus test on particular issues will not be given any applicants for the NIH Director's job?

Secretary **Sullivan**. I cannot guarantee that, Senator Bumpers. Clearly this happened in an instance I had no knowledge or control over. I can guarantee you that this is not the primary criterion for that individual, and the statement that I gave to the Association of American Medical Colleges was reviewed by the White House, so I was speaking with their concurrence.

Senator **Bumpers**. I accept that, and I thank you.

Senator **Harkin**. Senator, are you through on this line of questioning?

Senator **Bumpers**. No; go ahead if you like.

Senator **Harkin**. I was going to get into that later on, but as long as you are on it, we might as well finish it.

You repeatedly say, Dr. Sullivan, that it is not the primary criterion. Is it even a criterion?

Secretary **Sullivan**. My position on that, Mr. Chairman, is those issues are not appropriate for the consideration of the Director of our premier biomedical research enterprise. Those decisions are more appropriately made at a policy level beyond that of the Director of NIH and, therefore, that question of abortion and other similar questions are not governing questions.

On any range of issues, we want to be sure that whoever is chosen, is someone who indeed can be an effective spokesman for our biomedical research. We would look at that individual's compatibility with our overall programs. On the issue of abortion is not criterion for the selection.

Senator **Harkin**. Other matters you said relating to it, would that include fetal tissue research?

Secretary **Sullivan**. No; what I am referring to is we have a whole range of things that we are constantly dealing with such as how do we allocate the resources in our budget. There are always tensions and differences of perspective. What we need to have is someone who understands first of all not only the demands and needs of our biomedical research enterprise, but also how to work in a system where there are many competing demands.

Senator **Harkin**. But the attitude of a prospective individual to be head of NIH, the attitude of that person toward fetal tissue research, you say is also not a criterion?

Secretary **Sullivan**. That is correct.

Senator **Harkin**. Thank you, Dr. Sullivan.

Senator **Bumpers**. Thank you, Mr. Chairman.

Dr. Sullivan, Stalin demanded philosophical and ideological tests of scientists and when the war started, he killed off all his best scientists.

Of course, I am not suggesting a parallel case here, but I am offended that candidates for a job which is probably the premier biomedical job in the country would be asked to pass a test on abortion.

I am not an ideolog on this issue, but I hope you will do everything you can to make certain that an abortion litmus test is not the test for this job. I may be dead wrong, but I frankly think that was one of the things that caused Dr. Wyngaarden to leave, and I thought he was doing a superb job.

On more mundane matters, have you seen the article in the New York Times Sunday magazine on the impact of drinking on the fetus—I believe the research was done at Emory University?

FETAL ALCOHOL SYNDROME

Secretary **Sullivan**. I did not see that particular article, Senator Bumpers, but I am very familiar with the problem of fetal alcohol syndrome and the resulting problems.

Senator **Bumpers**. Of course we have all seen these horror segments on the news about crack babies, and it is a horrible thing. Of course the recent film from Romania of dozens of babies who have AIDS was heartbreaking.

Of course, we should be concerned about crack babies, but this article indicates that 2.7 percent of all the babies born in this country have learning disabilities as a result of fetal alcohol syndrome. I am just wondering if your Department, CDC, or any other agency, is trying to disseminate information on preventing fetal alcohol syndrome?

Here is a place where we are more likely to have great success with a limited amount of money. I would appreciate an update on what your Department is doing to address the problem of fetal alcohol syndrome.

Secretary SULLIVAN. Senator Bumpers, we are not only fully aware of the problem of fetal alcohol syndrome and other problems of prematurity, resulting from drinking but indeed we have a number of programs to address that problem, primarily at our Alcohol, Drug Abuse, and Mental Health Administration. The National Institute of Alcohol Abuse, is entirely committed to the problems of alcoholism in our society. We have a lot of research underway.

For example, our research is showing increasingly genetic influences in terms of predisposition to alcohol abuse, learning disabilities that you alluded to, low birth weight, et cetera. We also have a number of public education programs concerning alcohol abuse. Many of the facilities that we fund around the country deal with drugs and problems of alcohol abuse. We work with employers to support their programs for rehabilitation of individuals with alcohol abuse as well.

Senator BUMPERS. Dr. Sullivan, the most recent high school senior drug abuse survey gave us some comfort that drug use among high school seniors has been declining. It is not a big decline, but as I say, we can take some comfort in the fact that among high school seniors the use of drugs has been declining.

But the same report also shows a figure that was startling to me; that was that 35 percent of the high school seniors of this country, 17-year-old kids, said they had had five drinks or more in a row within the preceding 2 weeks.

Now, that would indicate that we have got a big alcohol problem among young people in the country, would you not think?

Secretary SULLIVAN. I am very concerned about problems of excess alcohol ingestion and, in fact, met approximately 4 weeks ago at the White House with a number of private organizations that are concerned with alcohol abuse and all of the related problems. Part of our health promotion program is to warn our citizens about the problems of drinking—in terms of impairing health, impairing ability to drive motor vehicles or to use machinery in factories, et cetera.

RECRUITING SENIOR SCIENTISTS

Senator BUMPERS. Dr. Sullivan, I am sure you are aware of the problems we have at NIH in recruiting senior scientists. I spent a day at NIH last year, and they told me that we had not recruited a single senior scientist in the last 3 years.

Dr. Wyngaarden suggested that was mostly because of the salary schedule. We apparently have been able to recruit senior scientists from within the ranks of NIH scientists. But salaries for senior scientists are apparently one of the biggest problems at NIH.

Secretary SULLIVAN. That is a significant problem, Senator Bumpers. We have not recruited a senior scientist in 10 years at NIH. We have a premier biomedical research institution, that has made many contributions over the years, that is in danger of being eroded if we do not address many of the problems there. Let me give one quick example of what I mean.

When I was a medical student in the mid-1950's in Boston, I took care of patients with paralytic polio in the epidemics in the summers of 1956 and 1957. Those individuals were in iron lungs. Changing their bed linen was a labor-intensive effort; we had to take them out of the iron lungs, assisting them to breathe, required the help of nurses, residents, and students.

At that same time Dr. Thomas Endes, a microbiologist at the Harvard Medical School was working in his laboratory with a grant of some $53,000 from the National Institutes of Health to find a way to grow the polio virus in the laboratory. He found a way to do this on monkey kidney slices. He received the Nobel Prize for that because that discovery then enabled Jonas Salk and Albert Sabin to develop the polio vaccine. Polio is almost now banished from the American scene.

But if you project from the mid-1950's to now what we would be paying in health care costs to maintain people in iron lungs; orthopedic and surgical corrective procedures, to try and correct withered limbs, to pay for wheelchairs, et cetera—that is just one example of the return that we have from our investment in biomedical research.

I am very concerned about salaries and other things in the environment at NIH that we need to address. I appointed a committee to help advise me on ways to make the NIH Director's position more attractive. Salary is important, no question. But there are some other reasons as well, and some of those reasons include the actions of the Congress.

Congress over the years has eroded the authority of the NIH Director by creating Institutes. We have said this is counterproductive, despite those recommendations, this has happened. Those Institutes have been created without increases in the number of FTE's at NIH, so it weakens the other Institutes when we bleed internally. When we move people from existing Institutes, we increase administrative costs, and it also erodes the authority of the Director when that individual in trying to develop a comprehensive research budget and policy has people running around him directly here to the Congress and then having mandates put in the budget for one of the specific Institutes.

I will be coming back to you and other Members of Congress once we have reviewed the advice from our committees with a whole range of things for which we will need your help on. Salary is one. That is very critical because we do have a three to fourfold interest in income for a scientist at NIH versus our universities or the private sector. But there is a lot more than that, and we certainly look forward to working with you on that.

Senator **Harkin**. If you could yield on that.

Senator **Bumpers**. I would be happy to.

Senator **Harkin**. I cannot let this moment escape, Dr. Sullivan. I understand your strong feelings about Congress setting up institutes, but it comes to my attention that last year you came down and wanted us to set up a human genome center, a separate center, which we did. That cuts both ways.

Secretary **Sullivan**. Senator Harkin, that is a center. That is not an institute.

What that is, is a position——

Senator **Harkin**. But it has the same administrative setup that an institute has.

Senator **Bumpers**. Dr. Sullivan, I am not sure that even needs an answer. I think the point is made that there is plenty of blame to go around. That is what the chairman is saying.

I would ask you who would you blame, for example, for a budget that asks for five airplanes that cost almost as much as all the Institutes of Health combined? Where do you put the blame on that?

Secretary **Sullivan**. Well, let us let this one drop, OK.

Senator **Harkin**. Could I bring up one other point on NIH?

I understand we have got to get the salaries up for the scientists, for the Director.

But, Senator Bumpers, I want you to also focus, if you could, on the need to get the salaries up for some of the postdoctoral people that come there to do research. These are the bright young scientists. They are interested in a certain area. A lot of them have been in school 8, 10, 11 years. They are in their thirties. They are probably married. They probably have one or two kids. They have all these school bills, and you know what they are paying right now at NIH for postdoctoral research? Correct me if I am wrong, but it is around $26,000.

Secretary **Sullivan**. That is correct.

Senator **Harkin**. How are you going to live in this area on $26,000 a year? There is no way you can do it. So, we have got to focus on that, too. These are bright young people that want to come in and dedicate a few years of their lives to researching a certain subject, a certain interest that they have and for that much money, we cannot get them.

Secretary **Sullivan**. I agree with you, Senator Harkin.

Let me just cite one other startling thing that I learned a few months ago, and that is that the visiting scientists who come and spend 1 year or 6 months or so on the campus of NIH, one-third of these are foreign scientists. We are training other nations' scientific leadership, and one of the reasons for that is indeed the salary structure; we have made it unattractive and almost impossible for some of our scientists to pursue a scientific career. I share with you that real concern, and I look forward to working with you as we try to address this issue.

NATIONAL HEALTH SERVICE CORPS

Senator **Bumpers**. Dr. Sullivan, I want to compliment you on recommending the funds for 750 student scholarships for the National Health Service Corps. We have very deep pockets of poverty in my State and in Mississippi and Louisiana, on both sides of the Mississippi River, in an area we call the delta. An area, by the way, where the per capita income is less than it is in Czechoslovakia. If it were not for National Health Service Corps doctors, we would have no health care in some of the most pervasively poor areas of America.

So I really applaud you for trying to resurrect a program which has great merit.

Now, Mr. Chairman, I just have two quick things.

The childhood immunization program has been a thing that I have tried to shepherd and look after ever since I have been in the Senate, to a large degree because of a devoted and caring wife who never lets me forget the subject. But this year, as you know, the Immunization Practices Advisory Committee has recommended a second measles shot. Last year we had 14,714 cases of measles. That is about four times the number we had in 1988. I am sure you are familiar with the advisory committee's recommendation of a second measles shot, either when the child starts school or when the child starts to college.

My staff tells me that getting the second shot to children in the public sector is probably going to cost close to $50 million in fiscal year 1991. Now, we must make some effort here to raise your proposal for immunization because we must give that second shot to all children. Now, that is a rollcall buzzer, and I will not pursue that further, Dr. Sullivan.

I will probably visit with you further about this issue. You know, everybody knows that the money spent on immunizations is the most cost-effective health care money the Federal Government spends. We simply must not shirk our duty there.

Two of the most intractable problems in this country are the 37 million people with no health care coverage and the spiraling health care costs.

Nobody really knows how to address those. It is just like the drug problem. We are just groping. We really do not know what to do. But there is something seriously amiss.

Now, Canada rations health care, but that may not be the worst thing in the world. Their longevity rates are higher than ours, and yet they only spend 75 percent as much per capita on health care as we spend.

Japan has a higher longevity rate than we have, and they only spend about 50 percent as much per capita on health care as we do.

Now, I just think that somehow politicians and the medical community are going to have to screw up their nerve and maybe make some unpopular decisions, but that is a real dichotomy to me that other countries have better longevity rates than we have, ensure universal access to care, and do not spend nearly as much money as we do.

Secretary **SULLIVAN**. As we review the reports coming forward this year from our task force headed by my Under Secretary Constance Horner, as well as the Pepper Commission and the Steelman Commission, we will be facing those very real issues.

I look forward to working those out with you because I fully share your concerns that we have a very expensive health care system that has serious gaps in it.

INFANT MORTALITY

Senator **BUMPERS**. Let me interrupt you. There was one other thing I want to get to before we leave here, and that is the issue of infant mortality.

The Governor and his wife in my State have been in the forefront on this issue for many years, and I have tried to be, too. Beginning April 1, States must offer Medicaid coverage to women and children who have 133 percent of the poverty level income.

I think we ought to be paying for Medicaid for women and children at least to 150 percent of poverty.

Secretary SULLIVAN. I will have to get back to you with that precise figure, but let me say this, Senator Bumpers. First of all, the President did propose, as you know, 1 year ago to raise it from 100 percent to 130 percent and, it has gone to 133 percent.

We were having discussions like this, but when the President met with the Governors at the education summit—I heard this directly—they praised things like Head Start, but they said uniformly "do not give us any more mandates, that our budgets are reeling, and we do not want this because this captures our dollars."

And quite frankly, Senator Bumpers, when that happened, the steam was gone out of our sales. The Governors really are saying that there had been too many Federal mandates.

Senator BUMPERS. Dr. Sullivan, I am not suggesting this be a mandate on the States. If a State cannot reach 150 percent with its funds, let them pay 125 percent or something of that amount, but those States who could pay on the basis of 150 percent ought to have that discretion. That was my point.

Are we still 18th in infant mortality in the world?

Secretary SULLIVAN. Senator Bumpers, the States already have the discretion to go as high as 185 percent.

Senator BUMPERS. You are telling me that if Arkansas agreed to provide neonatal and prenatal care for pregnant women, for example, newborns who have 185 percent of the poverty income, you will pay your normal share of that, is that correct?

Secretary SULLIVAN. That is correct.

Senator BUMPERS. Well, what is the 133-percent figure?

Secretary SULLIVAN. I am sorry?

Senator BUMPERS. What is the 133-percent figure?

Secretary SULLIVAN. That is a mandate. That is mandatory for all the States.

Senator BUMPERS. You do allow the discretion above that?

Secretary SULLIVAN. Mississippi is one of the States that has gone to 185 percent of the poverty level and there are a few other States as well.

Senator BUMPERS. Dr. Sullivan, thank you very much.

Senator HARKIN. Dr. Sullivan, there is a vote on the floor. I had hoped that we would finish everything.

Senator Specter has some additional questions that he would like to pursue with you. I may have a couple depending upon the time. We have three other agencies to come up to also.

I am going to recess the subcommittee when Senator Specter gets back. He will pick it up again.

The other two agencies who are to testify this morning, Family Support Administration and Office of Human Development Service, should go ahead and have lunch, and we will try to get you in this afternoon's hearing at 1:15. At that time we will also hear from the inspector general. So just be prepared to take a break and when Senator Specter comes back, he will pick it up.

[A brief recess was taken.]

Senator SPECTER [presiding]. Senator Harkin had asked me to resume the hearing, and I had to vote early to try to save your time, Mr. Secretary, so we shall proceed at this time, and Senator Cochran has been waiting, and we will turn to you now, Senator Cochran.

Senator COCHRAN. Thank you very much, Mr. Chairman.

Mr. Secretary, welcome to our committee again. I am grateful for the opportunity to be able to personally thank you for coming to Mississippi and making the commencement address at Jackson State University last year. You honored us with your presence, and we appreciate also the cooperation of your Department in helping to deal with some of the special concerns that we have in our State, one of which is trying to cope with the continuing problem of bringing health care services to small towns and rural communities. This continues to be a problem, and we appreciate your understanding of that.

And we hope that some policy can be developed and implemented to help these small town hospitals that are under such great pressures.

I know that we have seen some experimenting with conversions to alternative kinds of services. For instance, in Richton, MS, the hospital has built a long-term care wing onto the facility, and now they have moved into a conversion. So that hospital is not a traditional hospital as they knew, but it is providing some services that were not available in the community, and I do not know whether they are going to make a go of it or not financially and be able to sustain those services, but that is an example.

We have seen others experimenting with other kinds of services. I wonder what your reaction to that is. The plight of those towns and communities and what you may have in mind that we can go back and tell those who are trying to cope with this problem.

RURAL HEALTH CARE

Secretary SULLIVAN. Thank you, Senator Cochran. Thank you for your kind remarks. It was a great pleasure to not only visit Jackson State University, but several places in Mississippi to talk to the physicians and visit the Mount Bayou Medical Center in the rural part of the State.

We are very concerned about the issue of health care for citizens in rural areas, and there are several things that we have done to try and provide some support there.

First of all, through our National Health Service Corps program we give preference for the Health Corps personnel that we assign—physicians and others to both rural areas and inner cities. We anticipate with the proposed increase that we will have in the pipeline an increased number of health professionals for such areas.

Also, as part of our budget we propose a minority health initiative to train more minority physicians and other professional personnel. In a State like Mississippi where I think about 35 percent of the citizens are black, this would have a great impact in providing more health services.

In the hospital update that we proposed last year and which was approved by the Congress, we gave a greater update and the reimbursement grade for rural hospitals and also for large urban hospitals—that is, hospitals with 500 beds or over—because we felt that those two kinds of hospitals were under great stress.

As part of our physician payment reform, that the Congress passed last year, we are emphasizing a bonus payment to physicians in primary care in rural areas to make it more attractive.

We changed the criteria for sole community hospital status, hospitals with that designation would be reimbursed at national rates, giving them a higher reimbursement rate and where the criteria had previously been that the hospital had to be 50 miles away from the next hospital, we changed that to 35 so that a number of hospitals that had not been eligible could participate.

The Office of Rural Health Policy works with rural hospitals to help them find ways for administrative efficiencies and other improvements—we have increased their budget from $3 million to $4 million.

Those are some of the things that we have done to try and address the problem. This is an issue that is going to be part of our review and debate as we examine the reports coming to us and submitting to the Domestic Policy Council as President Bush charged me in the State of the Union Address.

What all of these things represent now are measures to help make adjustments in the system and keep things going. I envision a more comprehensive approach as we look at options that will be forwarded to us from our various committees.

Senator **Cochran**. I appreciate very much your personal interest in this and your leadership trying to help deal with these problems that we see in the rural areas and the small towns of our Nation.

One thing that I just wanted to bring up and get your reaction to is that the Public Health Service has come up with 21 steps, I think, that they suggest should be part of a national strategy to improve our preventive health effort.

As I see this increasing cost of health care problem, getting worse and not better, it seems to me that maybe what we ought to try is emphasizing preventive health care through suggestions such as the strategies developed by the U.S. Public Health Service.

Of course, stopping smoking and dealing with the alcohol and drug abuse are things that have been mentioned, and there are others. Is there any way that you think we could help you by supporting efforts through appropriations of funds to implement that kind of strategy nationwide?

Secretary **Sullivan**. Well, Senator Cochran. I think you are referring to our Health 2000 goals, which focus on prevention. As those goals are enunciated, we want to give them as wide a dissemination as possible, through the mailing of brochures to the entire population, public announcements on radio, television, et cetera, as part of our effort to both improve the health of our citizens and to control costs through active participation by our citizens.

We have a broad significant educational effort to do that which must be ongoing—not simply a one-shot effort or a 1-month effort. We have known since the early 1960's that smoking resulted in lung cancer. The first Surgeon General's report on smoking was issued in the early sixties. As you know, it was only in the last 6 or

8 years that we have now begun to see changes in the health behavior of our population.

We need to reinforce that. What I am saying is, a health education effort must be an ongoing sustained effort and not simply an effort for 1 year, but really continued through many years.

HEALTH CARE FINANCING ADMINISTRATION

Senator **Cochran**. I know that our Medicaid and Medicare Programs have the big challenge of trying to keep people happy in terms of reimbursements and timely response to inquiries and the like from health care providers.

Just this week I had a chance to meet with a group of providers from my State, and a common complaint I heard was the fact that there are delays and unnecessary delays and problems in dealing with the Health Care Financing Administration.

I know we have an opportunity to talk to them later today, as I understand it, and I will bring this up, but I just wanted to mention it as something I hope at your level there can be some emphasis placed on being more responsive to the hospitals and those who file their vouchers or forms for reimbursement.

There seems to be a tremendous amount of tension and dissatisfaction that is developing, at least in my State over this issue. Maybe it is the provider's fault, I do not know, but somebody needs to look into it, and I hope you will ask for a report on that and see how quickly they are making those checks out and sending them back.

They have the suspicion down home that they sent in their voucher and there is somebody up here that tells them to hold them and sit on them about 3 weeks before they process them, that that is a way of delaying payment and getting better budget numbers to send to OMB or somebody. That is a suspicion out there, and we need to deal with that.

Secretary **Sullivan**. Yes, Senator Cochran. We indeed are very concerned about that, the new HCFA Administration, Dr. Gail Wilensky, shares this concern. We are very pleased that she is on board. This is one of the areas that we have identified as needing attention.

We are required to make those payments, I believe, within 24 days of the receipt of the voucher. Until this year we actually were also mandated by the Congress to make the payments—between 14 and 24. The requirement for holding claims for 14 days prior to payment expired at the end of fiscal year 1989.

We are making efforts to make those payments sooner when we get our systems working.

Senator **Cochran**. Thank you very much.

Thank you, Mr. Chairman, for the time.

Senator **Specter**. Thank you, Senator Cochran.

Dr. Sullivan, I have just a few more questions that I would like to discuss with you. Senator Harkin has asked me to proceed, and I think this will wrap it up.

I have taken a look at the two facilities which you had described, checked with them, and I am aware of what has been undertaken with respect to Washington House, which was a Department of Defense facility transferred to the city in 1985 that I had worked on. There is an additional homeless women's facility which was established in May 1988 as a small, 20-bed facility, and this is really separate from the request which I had discussed with you last year and have been made a part of the Senate report accompanying the Labor, Health and Human Services, and Education appropriation bill on page 182 (S. Rept. 101-127) there is a reference to the committee having provided $9,090,000 for a homeless research demonstration project, and it enumerates a number of factors, including detoxification services and referenced on the same page problems in cities such as Philadelphia. So, I just want to round that out by saying this is different, and I would very much appreciate your attention to this one as soon as we can process the application.

Secretary **SULLIVAN**. I will give it my personal attention. We want to do everything we can to be sure that the response in our agency is as rapid as possible.

Senator **SPECTER**. I would appreciate that.

You had commented that there had been a delay on appropriations, and I had questioned that and I was told that it is a general practice to await the appropriations process. I ask you to review that, as to whether it is necessary to await the final appropriation, where you have a project as important as this one.

But, at any rate, we are on track now, so I would appreciate your attention to it.

DRUG REHABILITATION

Dr. Sullivan, last year I had brought up the subject with you which I had raised with your predecessor, Dr. Bowen, the year before, regarding what rehabilitation works on the drug issue. When Dr. Bowen was here in 1988, there had been a comment that they did not really have much to rely upon in the way of experience as to what was successful.

As I had expressed to you last year, this is a concern I have had for more than two decades since the founding of drug rehabilitation centers that I helped with in Pennsylvania in 1968. I am interested to know, and you might want to submit this in writing since time is short, and it is past noon, as to what progress has been made on the identification of treatments which work.

You had submitted a written answer for the record last year, and there had been some preliminary information, but there were more projects to be evaluated, and I would be very much interested to follow this up not only with a written answer now, but with continuing responses so we can evaluate just what we are accomplishing by way of finding out what does work.

Secretary **SULLIVAN**. We will be pleased to submit that to you. I am pleased that with the increased funding for demand reduction activities will provide significant increased funding for research on new types of therapy.

[The information follows:]

METHODS OF TREATMENT

I share your concern in determining what methods of treatment are effective. Dr. Charles Schuster, Director of the National Institute on Drug Abuse, will provide the committee with a report on treatment method effectiveness. In August, 1989, a technical review was sponsored by NIDA on "Improving Drug Abuse Treatment". A full report of what was discussed at the technical review will also be included in Dr. Schuster's report to the Committee.

MENTAL HEALTH

Senator SPECTER. Well, there had been that direction in the 1988 legislation giving your Department a new responsibility. If we can document programs which work on rehabilitation, I think that the Congress would be very interested in increasing funding.

Dr. Sullivan, the next point that I want to take up with you briefly is the issue of mental health, and I do not know that there is a whole lot to be said about it except that we really need to search for additional funding. I ask your assistance on that as Senator Harkin and I and others try to find more money for that very important line.

There is a lot of sentiment in Congress for increased funding because there have been so many breakthroughs and it seems so productive to utilize those funds at this time.

Secretary SULLIVAN. Senator Specter, I share your concern. I was pleased that Congress passed the resolution to declare 1990 the decade of the brain. We have proposed in our budget $99 million for research in schizophrenia. We believe that much remains to be done. We look forward to working with you as we expand our research and our understanding of mental disorders such as Alzheimer's disease.

Senator SPECTER. Very good. We will look forward to doing that.

The next topic that I want to just touch on is this issue of crack babies. I recently visited St. Francis Hospital in Pittsburgh, where there has been a grant of some $1 million, and there is very important research being undertaken on women who are addicts are giving birth, Thomas Jefferson Hospital, where there is a special pediatric AIDS program and St. Christopher's Hospital in Philadelphia. Again, we are balancing many needs for funding, and we are trying to find answers through limited funds for pilot projects, and I just wanted to mention that we will be following up with you on this matter of expanding on present efforts.

Secretary SULLIVAN. Thank you.

GAUCHER'S DISEASE

Senator SPECTER. Now, the final subject I want to talk to you about—and there are many, many like these, but I had a contact on a special problem relating to a disease known as Gaucher's disease. And the President of the Gaucher's Foundation, Mr. Michael Epstein met with Dr. M[illegible]ray Goldstein, Director of the National Institute on Neurological Disorders and Stroke and Dr. Ross Brady, head of the Gaucher's disease intramural research program at NINDS.

What this boils down to is that they need additional enzyme for clinical treatment to determine the appropriate dosage, as I understand it, for a treatment of Gaucher's disease, which affects some 15,000 to 20,000 children nationwide.

It comes down to a need to find $2.5 million to buy the enzyme, and among the many, many requests which have crossed my desk, I thought this one was worth a few moments of our time here today.

They talk about a supplemental appropriation, but I do not know where or when, and the question arose as to whether this might be important enough for an effort by you personally. In your Department with your budget, I am aware, even as big as your budget is, you do not have much loose money lying around. But what I would ask you to do is to review this personally and see if you might find the funding, $2.5 million, to make this enzyme purchase which would enable this testing program to go forward.

Secretary **Sullivan**. I will be happy to review that and see if indeed there are any funds that we could give. Gaucher's disease is one of the lipid storage disorders that causes all kinds of problems, and if a way has been found that suggests a therapeutic approach, we certainly would be interested.

I am not familiar with the details, but I will review that and see if we can be of help.

Senator **Specter**. Well, thank you very much, Dr. Sullivan. As usual, you are very responsive and helpful.

We talk about so many problems and when they come to our attention we all try to do the best we can with so very many demands and such limited resources, and we thank you for your high level of professionalism. It is a pleasure to work with you, and we will keep plunging ahead. Thank you.

Secretary **Sullivan**. Thank you, Mr. Chairman.

AIDS

Senator **Harkin** [presiding]. I have a couple of last things I want to go over. One has to do with AIDS and AZT. We included $29.6 million last year for AZT, $19.7 million for home health care, $1.5 million for subacute care. None of these have been funded in your request.

Particularly with regard to AZT in view of what I said in my opening statement about the new findings with regard to AZT, and last year your own department estimated that 248,000 HIV positive individuals would come down with AIDS between 1989 and 1992.

What is your strategy—if you do not request money for AZT or for home health care or subacute care, what is your strategy to deal with the need for AZT and other drugs for people who are HIV positive but cannot afford any treatment or do not have insurance to cover it?

Secretary **Sullivan**. Senator Harkin, I actually have difficulties with the concept of designated drugs for treatment. We don't fully understand the dimensions of the problem. I want to assure you we are committed to doing everything we can to address it.

We feel that it is more appropriate to have those funds in our general care dollars, that is, Medicaid and Medicare. Individuals, who are eligible for support are provided that drug through those programs.

We want the greatest possible flexibility with the dollars that we have because, while today we may have a problem, say, with AZT or AIDS, 5 years from now it may be some other problem. Once we start having categories of dollars for specific drugs, it really gives administrative problems.

Senator HARKIN. OK, I understand that, but how about people who are HIV positive and—their assets may be a little bit more than what qualifies them for Medicaid, yet they may not have health insurance? And I know you have to spend down to be eligible for Medicaid. I mean, you have to spend everything down to get there.

Do you have any plans to deal with this? As I understand it, some of this AZT money was for filling in that kind of a gap. You said Medicaid would take care of it. That is true, once you get down to that—spend down to that level that qualifies you for Medicaid. Is that what you are saying, that these individuals should do that?

Secretary SULLIVAN. I think this really falls under the category of how we organize our health care system. Our programs are designed to provide funds for those who are most vulnerable in our population. However, we do have problems such as what you have alluded to.

That is one of the kinds of issues that we are reviewing as we examine options for potential reforms in our health care system. A similar question applies to the whole issue of long-term care: To what degree does the individual have a responsibility for providing their resources either through insurance or their other resources versus societal responsibility.

Clearly, while I do not have an answer, that is one of the kinds of questions that we are wrestling with as we look at options that are going to be coming forward for our national discussion and debate.

Senator HARKIN. Your 1991 budget estimated there were 600,000 to 1.4 million HIV infected persons in the United States. Last year we were told the estimate was 1 million was to a 1.5 million. Do you have any knowledge of why you lowered your estimates?

Secretary SULLIVAN. We are not really sure yet what all of the factors are. We have had tremendous success, particularly in our homosexual population, with our educational efforts to try and change high-risk behavior. Experts in the department feel this may be the result of progress that we are making.

I am sure you read, as I did, a couple of days ago that we are not seeing that kind of improvement with the IV drug abuse problem, resulting in AIDS in that segment of the population. We have not had that kind of success with behavior change in that population. Whether there are other factors, we do not yet know. Our figures have been revised toward a lower amount.

RURAL HEALTH CARE

Senator HARKIN. Let me turn briefly to rural health care. Last August the National Advisory Committee on Rural Health forwarded to you its recommendations to improve health care. They had a number of recommendations that I will not go over here. But none of the initiatives that they proposed is in your budget. And I am wondering why.

I will just read some of them: implementing Federal grant programs to promote integration and coordination of services in rural areas, increasing Medicare payments for rural primary care physicians, revitalizing and expanding the National Health Service Corps scholarship and loan repayment programs, which is what Senator Bumpers, I think, brought up.

But none of those is in your budget, and I would like to have you, if you could, you or your staff, sort of flesh out for us more of the different rural health care initiatives that you feel are sort of subsumed into this budget that you have sent up to us. I would like to take a look at that.

Secretary SULLIVAN. I will be happy to respond in writing. First of all, Senator Harkin, I have met with Governor Ray, the chairman of that committee, last November, and that was very helpful. We do have in our budget submission some beginning responses.

[The information follows:]

RURAL HEALTH CARE INITIATIVES

We have begun specific initiatives within the Department in response to the National Advisory Committee on Rural Health. Already in 1990, the National Institute of Mental Health has created the Office of Rural Mental Health Research and a search committee has been formed to recruit a director. HRSA will fund two new rural health research centers this year which will collect, analyze, and disseminate information on rural health issues of national significance, with one of these centers focusing specifically on the health problems of rural minorities. HCFA also has a new wage survey underway which will help refine Medicare hospital wage index adjustments under the prospective payment system. We expect this information to be available for use in 1991. In addition, I plan to submit a legislative proposal this Fall which will establish a single standardized Medicare payment rate to all hospitals by 1995, effectively eliminating the urban and rural hospital payment differential.

In 1991, the budget also includes funding for a number of activities which address committee concerns. The Medicare hospital capital payments reduction of 15 percent for rural hospitals is more lenient than the 25 percent proposed for urban hospitals and we expect our 1991 proposal to restructure physician payments to benefit rural physicians. As part of the Minority Health Initiative, we also expect the proposed increase of $55 million for the National Health Service Corps Scholarship and Loan program to provide health professionals to underserved rural communities. We have also proposed an increase of $9 million more than in 1990 to increase access to health services through Community and Migrant Health Centers and an increase of $1 million to the Office of Rural Health Policy to provide technical assistance to rural hospitals.

NATIONAL HEALTH SERVICE CORPS

Secretary SULLIVAN. For example, we have expanded National Health Service Corps dollars in our budget. We proposed, of course, as you know you and the other members of the Congress did pass physician payment reform this past year. In that is a provision that gives a greater reimbursement rate for rural-based physicians in primary care.

The problem is that that program does not really come online until 1992. It is not reflected in this year's budget, but the response to those recommendations is underway.

FAMILY PLANNING

Senator HARKIN. Let us turn to family planning services. I can give you a number of statistics about Iowa. In 1984 one out of every eight births in Iowa was to an unmarried woman. By 1988 that number had gone to 1 out of every 5.7 births. The Business and Industry of Council of Iowa found teenage pregnancy to be the major factor in the State's welfare roles. I can go on down all these stats, but I will not bother you with those.

What I am pointing out is that title X family planning and contraceptive services have been cut for Iowa by 17 percent in the last 10 years. You can see all these numbers going up, but the title X family planning and contraceptive services is cut 17 percent.

Given what I feel is the cost effectiveness of the title X program and a devastating human and financial toll of unintended pregnancies, would you support an increase in title X funding? Initially, it looks like your proposed budget is essentially flat for this program in 1991.

Secretary SULLIVAN. This as well as other programs in our budget is obviously competing for priority. Let me assure you that we are committed to family planning, to giving information to young people, and anyone in the population who has a need for these services.

We support family planning but felt that keeping level funding was adequate. If there are problems that are the result of that judgment, we are willing to take another look.

Senator HARKIN. I wish you would, because as I understand it the budget you have sent for title X is flat from last year. So if you put in inflation, it is really another cut. Last year, in Iowa we went down 17 percent, this would cause it go down some more this year. And this is true in every other State.

I have heard you talk about this as being one of the best ways to attack the whole issue of abortion in our society. This is one of the best ways to do it, right there, title X: money for family planning and contraceptive services.

If you have any further thoughts on title X funding, or if you would like to request any more, ask us to boost that up, I would like to know about it.

But is your position basically that the flat level of what you received last year is adequate to do the job?

Secretary SULLIVAN. Mr. Chairman, I have just been informed by my staff that support for family planning has actually increased by some $18 million in our Medicaid budget from $273 million to $291 million. While the funding is flat in the designated family planning program, we provide greater funding through the Medicaid Program for family planning.

There is an $18 million increase in that category in Medicaid.

Senator HARKIN. I was just discussing with the staff the differences in those two programs. And evidently this Medicaid Program is a State reimbursement program. It reimburses the States for the activities they do. It is a 50-percent matching program, but it varies from State to State.

And of course, if States want to do it, they can. If they do not, they do not. So, there is no Federal mandate in that at all that the States have to do it, whereas that is all the program does.

But we will look at that. That is interesting. I am glad you brought that up.

You mentioned medical treatment effectiveness, and again, I just want to compliment you on that and hope that we can increase that initiative. You went from $32 million to $49 million, and that is good. And we will take a look to see if that is adequate, but I think you are on the right track on that.

HUMAN GENOME FUNDING

The human genome plan. We put in the money you have requested: $108 million. It is about twice what we had last year. Not quite. I guess what I want to ask is can we collapse the timeframe on this?

In other words, we are looking at funding out for about 15 years. I have been led to believe, you can correct me if I am wrong, that really we know what to do in mapping the human genome. It is going to take people. It is going to take these big super computers and lab space and money. And the more you put into that in the beginning, the faster timeframe we can complete it in. Am I wrong in that or not? I do not know.

Secretary **SULLIVAN**. No; I agree with you, Senator Harkin. As you know, we project this program when it is fully developed to be around $200 million annually. Last year we requested $100 million and received $60 million. This year we have requested $108 million.

We agree that the more quickly we can come up to speed the better. It is going to take time to get the personnel on board, facilities in place, et cetera, to get us up to the $200 million level. The $108 million figure is what we feel we can effectively utilize this year. We hope that with your help, we will get the full $108 million this year. And then, I can assure you, I will be back here next year asking for an even greater increase.

We feel that with our budget constraints, it does not make sense for us to request for more money than we can effectively use in developing this program. But we are committed to having that program up and running as quickly as possible.

Senator **HARKIN**. Senator Inouye has been chairing another hearing and could not be here. He just wanted to pass on his thanks to you, Dr. Sullivan, for including $2 million in the budget for native Hawaiian health care programs. He just wanted to express his thanks.

Secretary **SULLIVAN**. We are pleased to do that, Mr. Chairman. We are fully aware that the native Hawaiian community has very severe health problems. We are committed to addressing those kinds of needs where they do exist in our population.

I had an opportunity in July of 1988 to visit several of the health facilities in Hawaii as a member of the National Cancer Advisory Board and was concerned that native Hawaiians have one of the highest incidence of cancer in our population and other problems as well.

So, clearly, we think that this $2 million will be money well spent.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Mr. Secretary, I have additional questions for the record from Senator Rudman, Senator Graham, Senator Byrd, as well as committee questions for you to respond to.

Secretary SULLIVAN. I will be pleased to respond to you.

Senator HARKIN. Mr. Secretary, thank you very much for your generous time.

Secretary SULLIVAN. Thank you, Mr. Chairman.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

POVERTY PROGRAMS

Question. Once again, you are proposing deep cuts in the Low Income Home Energy Assistance Program (LIHEAP), the refugee programs, and total elimination of the Community Services Block Grant. Why do you choose to cut the programs which serve the poorest of the poor within the Department of Health and Human Services?

Answer. We are not proposing any funding reductions in the Refugee and Entrant Assistance program. Rather, we are seeking $369 million, the same level as Congress appropriated in 1990. This amount would continue the current periods of special benefits and subsidies of State costs.

In the case of low income energy assistance, inflation-adjusted heating prices are expected to be below pre-LIHEAP levels.

In the case of the Community Services Block Grant, we still request $42 million, the full authorizing level, for the Emergency Community Services for the Homeless. We believe similar services to those provided through the CSBG exist in other Federal program areas. In fact, in several such areas, expansion and substantial funding increases are being requested for programs that are targeted at the poor such as the JOBS program and Head Start.

Question. Do you consider these cuts necessary to pay for selected increases in programs such as Head Start and biomedical research?

Answer. No. The cuts in these programs are not based on other increases in the budget. As prudent managers, it is time to reassess the Federal Government's financial role for these programs.

Energy assistance became a major program in FY 1980 in response to the 1979 oil price increase and 1980 natural gas price increase. This program supplemented the existing assistance for low-income persons. During the 1980s home energy costs have moderated. In 1991, inflation-adjusted heating prices are expected to be below the 1978 level.

The **refugee resettlement** funding level, the same as fiscal year 1990 is intended to provide resettlement assistance to 110,000 new refugees, the State Department's estimate. This will continue the current rate of subsidies of the States' share of cash and medical assistance for categorically eligible refugees and the current benefits for non-categorical refugees. Also, in an effort to further emphasize self-sufficiency, the Department has requested $75 million for employment services.

Congress initially estimated that a total of $4 billion for **State Legalization Impact Assistance Grants** (SLIAG), over a four-year period would be necessary to meet added Federal and State costs for the legalization process for aliens. Welfare costs through 1992 will be a billion dollars less than expected. Based on recent State data on actual spending patterns, this earlier estimate of need seems to be excessive. Last year, after much debate, the Congress concluded that the original SLIAG appropriation was over-estimated, and reduced the amount for fiscal year 1990.

The **Community Services Block Grant** (CSBG) replaced the community services direct grants in 1981. Now that community action agencies are well established, they should be able to provide services on the same reimbursable basis as other providers. Moreover, since that time, there has been expansion in programs such as welfare reform employment services and child development. Therefore, the budget eliminates CSBG, and increases funding for the homeless program, authorized by the Stewart B. McKinney Act.

FY 1990 HHS TRANSIT INITIATIVE

Question. Mr. Secretary, last year, Congress appropriated $250,000 to the Department to establish a program to provide technical assistance to DHHS-funded human service agencies providing transportation to their clients.

What is the current status of that initiative and what steps are you taking to implement this new program?

Answer. The Department of Health and Human Services (DHHS) and the Department of Transportation (DOT) have signed an agreement which funds an initiative providing the following:

(a) technical assistance and a support structure that will provide assistance to State and local DHHS-funded program that provide specialized and human service transportation services; and (b) a report to the Secretary of DHHS that will identify and assess human services transportation issues and needs at the Federal, State and local level and recommend actions and strategies which will address those needs. This project will be conducted under the auspices of the DOT/DHHS Human Service Transportation Coordinating Council and the overall direction of DHHS. The Urban Mass Transportation Administration (UMTA) in DOT will manage the project and select an UMTA grantee to conduct this project.

Question. What provisions have you made in the FY 1991 budget submission to continue this initiative?

Answer. The Department has not included a specific request for direct funding of this initiative in the 1991 Congressional submission, pending the results of the report to the Secretary requested in the 1990 appropriations bill. We will continue to implement joint DHHS/DOT transportation initiatives through the Coordinating Council, and any necessary funding will be sought from the appropriate DOT and DHHS components. Any additional need for direct funding of this initiative will be included in the 1992 budget request.

Question. Would you outline for the Committee the Department's current efforts to improve the overall coordination of Federal transit resources and programs?

Answer. For some time, this Department has been actively involved in promoting improved coordination of Federal transit resources and programs for our constituents. Consequently, on October 24, 1986, DHHS and DOT entered into an agreement to work together to improve the efficiency and effectiveness of human service transportation services through better coordination of transportation services at the Federal, State and local levels. In order to ensure effective and coordinated administration of this initiative, DOT and DHHS established a Federal Council on Transportation Coordination consisting of representatives from staff and operating divisions of the Departments to implement this agreement. The 1990 Council workplan has been approved and adopted, and agency meetings are being held for the development of more detailed action plans.

JOBS TRANSPORTATION

Question. In adopting the Family Support Act of 1988, Congress recognized the importance of mobility in assuring that public assistance recipients have meaningful access to training and employment opportunities. Under the Act, States are required to assure the availability of adequate transportation and other support services needed for access to the mandated JOBS program.

Mr. Secretary, in view of the fact that almost half of the rural counties in this country have no public transit services, what initiatives has the Department taken or is considering to assist States in meeting the basic transportation needs of those families participating in the JOBS program?

Answer. Transportation costs to participate in JOBS are eligible for Federal reimbursement. However, we believe, that the States are in the best position to determine how to meet their individual participants' transportation needs. As a result, the Department has attempted to provide States with maximum flexibility to decide how they will use available JOBS dollars to meet transportation needs. At this time, HHS has not undertaken specific initiatives that address basic transportation needs of families in JOBS.

Question. Could you provide this Committee with an analysis of State plans under the JOBS program that have been submitted to the Department, outlining their approaches to the transportation problem?

Answer. States are not currently required to include information on their approaches to JOBS transportation problems in their initial JOBS State plans. Therefore, we cannot at this time provide you with the analysis you have requested. States will be required to provide a statement of their transportation policy as part of their final FY 1991-FY 1992 State plans which are now being developed. However, these statements will only contain information on the types of transportation for which States will provide reimbursement and the rates of reimbursement for each type of transportation.

Question. Is your staff exploring ways of cooperating with the Department of Transportation or other agencies to assure the provision of needed transit services? For example, would you consider supporting a joint employment transportation initiative with DOT to demonstrate effective ways of coordinating resources and sharing Federal responsibilities?

Answer. We are always interested in cooperating with other agencies to improve program operations in areas of cross-cutting responsibility. In working with States which are implementing JOBS, we have coordinated our efforts closely with those of the Departments of Labor, of Education and of the Interior. However, since the bulk of JOBS dollars go to the States, and because each State's transit problems are unique to that State, we believe that States should have the flexibility and the funding to address these problems directly where possible.

CONTROLLING MEDICARE COSTS

Question. The reconciliation legislation passed by Congress last fall established expenditure targets for Part B Medicare costs in an attempt to control double digit annual increases.

Tell us how this legislation is being implemented, and what it will actually mean for Part B cost containment.

Answer. As you are aware, we published in the Federal Register on December 29 the Medicare Volume Performance Standard (MVPS) for FY 1990. We are currently developing the MVPS for FY 1991, and I will be sending a recommendation on it to the Congress in April.

The MVPS does not in itself reduce the amount that will be spent. It is intended to give us and the Congress an objective criterion against which we can measure and assess the rate of spending for physician services under Part B of

Medicare. Consequently the MVPS helps in determining what the appropriate level of increase in payment for physician services should be.

In the past, attempts to hold down the rate of Part B spending have been in part thwarted by increases in the volume of services provided. Since the MVPS will make the medical community as a whole more conscious of this trend, we anticipate that physicians will exercise restraint in the provision of questionable or unnecessary services.

CHILDREN IN POVERTY

Question. According to Census Bureau statistics, one in five American children lives in poverty: 12.6 million children below the age of 18. Among Blacks and Hispanics, two in five children are impoverished. Many lack health care.

Despite six years of economic expansion, why do so many children remain in poverty in the richest nation on earth?

Answer. The stubbornly high continuing incidence of children in poverty in this country has its roots in such problems as the growing number of teen mothers and single parent households, increased substance abuse, and low educational and job skills.

Although a strong economy is a necessary ingredient to fighting poverty, economic expansion has a reduced effect on individuals and their families who lack the training and job related skills to be competitive in our technologically complex marketplace. As a result, even though we have shown great success in the past twenty years in reducing poverty among other groups like the elderly and the disabled, we have had noticeably less success in raising children out of poverty.

Question. Do you think a lack of child care is a major impediment to helping children out of poverty, by keeping single parents from working?

Answer. Reflecting its concern that lack of child care might impede helping children to get out of poverty, Congress, in enacting the Family Support Act of 1988 (P.L. 100-485), provided both for child care to AFDC participants in the JOBS work and training activity, and for up to 12 months of transitional child care for AFDC recipients who leave the welfare rolls due to increased earnings. Funding for these two types of care is projected at $206 million in FY 1990, and $489 million in FY 1991; funding for both types of care is open-ended.

Question. What needs to be done to get children out of poverty in the United States?

Answer. Children need to receive support from both parents, and especially from an absent parent. The Family Support Act embodied a new consensus between the Congress and the Administration that the well-being of children depends not only on meeting their material needs, but also on the parents' ability to become economically self-sufficient. Self-sufficiency and family responsibility are critical to reducing the number of children in poverty in the United States. To help to get children out of poverty several fundamental needs must be met.

Basic education is one of the most important tools an individual needs to achieve independence and self sufficiency. Programs like Head Start can give poor children a boost an additional chance to overcome the educational deficits which currently hold so many children in poverty.

Women and their children represent the overwhelming proportion of AFDC recipients; within this group the most dependent are never-married mothers who did not finish high school and who had their first child at a young age. Work and training programs like the recently enacted JOBS program can help to address the needs of this group.

A strong commitment to programs such as Child Support Enforcement help insure that parents retain the primary responsibility for the support welfare of their children.

Finally, Aid to Families with Dependent Children and related income maintenance programs are being tailored both to meet the income needs of individuals served and to help these individuals achieve economic self-sufficiency.

Question. Can we realistically expect programs of the Department of Health and Human Services to make a dent in reducing poverty?

Answer. Programs supported by the Department of Health and Human Services address several of the fundamental problems that result in poverty--illness, disability, aging, limited job skills, and parents abandoning their financial responsibility to their children. HHS programs provide services for those most in need through programs such as Aid to Families with Dependent Children (AFDC), Medicaid, Child Support Enforcement, Supplemental Security Income (SSI), Head Start, and the Social Services Block Grant. As a recent report by the House Select Committee on Children, Youth, and Families noted, "of the 25 percent of all children who are considered to be in poverty before receiving public transfers, 21 percent are lifted out of poverty as a result of this assistance." This represents a sizable reduction in poverty that we are quite proud of. The programs administered by the Department of Health and Human Services target a wide variety of problems which face families in poverty.

HEALTH INSURANCE

Question. What proposals do you have to extend health insurance to all workers in this country?

Answer. The problem of the uninsured is one of the major health policy issues facing our country today. The Department budget does not contain any specific proposals related to health coverage for uninsured workers because I am waiting for recommendations from a number of groups which are studying this issue. In his State of the Union address, the President instructed me to lead a Domestic Policy Council review of recommendations on the quality, accessibility and cost of our nation's health care system.

In June, I appointed the Quadrennial Advisory Council on Social Security. The Advisory Council is a bi-partisan group representing business, labor, health care providers, politicians and private citizens. The group will study the issue of the uninsured and will submit their report and recommendations later this year, with interim recommendations relating to the uninsured as soon as possible.

In addition, Under Secretary Horner is chairing a Department task force that is examining the problem of those lacking insurance. The task force will look very carefully at different approaches to this problem, including extending Medicaid to the uninsured, and will provide a report recommending reasonable and cost effective approaches later this year. Finally, the Pepper Commission is expected to report its recommendations on health insurance for the uninsured in March.

Once we receive the recommendations of these various distinguished groups we can begin to asses the options that are available for addressing this most pressing and very complex issue.

MEDICAID

Question. Do you favor expansion of Medicaid to cover the unemployed who are currently not eligible and without health insurance?

Answer. As part of OBRA 1989, States are mandated to extend Medicaid coverage for pregnant women and infants with family incomes up to 133% of the Federal poverty level. States must also add mandatory coverage for children ages 1 to 6 with family incomes up to 133% of the poverty level. We have not proposed an additional Medicaid eligibility expansion this year because we feel that we need to give the States some time to implement the many new Medicaid expansions that have been recently enacted. We continue to encourage States to use existing authority for optional coverage of pregnant women and infants with family incomes up to 185% of poverty.

The problem of the uninsured, however, is one the major public policy issues in health. I have been looking extensively at the question of the medically uninsured since I began my tenure at the Department. As I have mentioned, there are several groups studying the issue of how best to provide health care for the uninsured, whether through Medicaid or some other mechanism. I have specifically instructed the Advisory Council on Social Security to produce interim recommendations as soon as possible on health financing issues relating to the uninsured, with particular emphasis on Medicaid. I intend to wait for the recommendations from these groups before I proceed with specific proposals. In his State of the Union address, the President instructed me to lead a Domestic Policy Council review of recommendations on the quality, accessibility and cost of our nation's health care system.

POOR FINANCIAL MANAGEMENT

GAO has called for government-wide improvements in financial management systems. There are reportedly billions of dollars of differences between balances recorded in accounting systems and financial reports.

Question. What is your assessment of weaknesses in financial management of your agency?

Answer. The weaknesses in financial management at the Department of Health and Human Services can be directly attributed to the antiquated financial systems currently in place. These systems are labor-intensive, relying heavily on manual processing and report preparation. Also, they are not properly linked to one another (e.g., procurement and core accounting). These deficiencies have led directly to the reconciliation problems recently reported by GAO.

Question. What specific areas could be strengthened, and what is your plan for making improvements?

Answer. Improvement of financial management systems is a major HHS initiative. The Department is implementing the Phoenix Project, which is aimed at strengthening HHS financial management systems by:

o continuing to improve and standardize budget and financial information systems and processes for greater operating efficiencies and control;

o consolidating financial information into an agency-wide perspective as required by OMB Circular A-127;

o implementing the Federal government's Standard General Ledger in HHS;

o modernizing our automated financial management systems and those administrative management functions which provide data to Financial Management; and

- further improving compliance with OMB/GAO requirements and the Federal Managers' Financial Integrity Act.

The HHS plan addresses the need for the timely implementation of actions to address these priorities as they affect automated systems, whether wholly within the Phoenix structure (e.g., the Operating Divisions' Accounting System) or interfacing with it (e.g., the Personnel Payroll System).

The basic concept for the Phoenix Project derived from the Federal government's Reform '88 initiative, which sought to reduce inefficiencies in the operation of governmental administrative and financial systems, and to promote improved decision-making, accountability, and system integrity controls.

Question. Do you agree with GAO's assessment that managers need more and better training in Financial Integrity Act issues?

Answer. The Department agrees that training is a key element in implementing an effective FMFIA program. In this respect, the Chairman of the Council on Management Oversight has already requested HHS' Assistant Secretary for Personnel Administration to develop a comprehensive, Departmentwide FMFIA training program. In addition, the Director of the Department's FMFIA Program has been working with the Office for Civil Rights and the Family Support Administration in a separate effort to train their staffs under the auspices of the Office of Personnel Management.

HEALTH CARE COST TRENDS

The continued rate of increase in health care spending -- for the economy as a whole and for the federal budget -- remains much higher than the general rate of inflation as measured by the consumer price index.

Question. What recommendations do you have for addressing these increases and where can federal policy make the most difference?

Answer. First, I would like to point out that Medicare and Medicaid can address only a portion of our national health care needs and costs. But, as you know, there are several studies currently under way which will be providing recommendations for more comprehensive approaches to meeting our national health care needs, especially for the uninsured and long term care. In addition to the Pepper Commission and the Steelman Advisory Council, I have directed the Undersecretary of Health and Human Services to conduct an examination of these issues. Once the results of these studies are available, the President has directed me to coordinate a Domestic Policy Council review and consideration of their recommendations in order to develop a comprehensive and cost effective set of proposals for meeting the health care needs of our nation.

But we are not just waiting for those studies. Some things are already in place or in preparation. As you know, a few years ago, we implemented the prospective payment system for Medicare Part A hospital payments. Under this system hospitals are paid a predetermined amount for each procedure based on the cost of delivering that care. If the hospital delivers the care for less the PPS amount they keep the excess; if it costs them more than the PPS amount, they must absorb the extra cost. This approach gives the hospitals a strong incentive to find more efficient ways of providing care. PPS has generally been quite successful in restraining the previously excessive rate of growth in hospital care costs under Medicare.

Beginning in 1992, we will be implementing a major reform in the way Medicare pays for physician services under Part B. This reform is similar in concept to PPS for hospitals. A fixed amount is set for various physician services based on the cost and amount of resources required to provide the service. It is anticipated that this will result in a significant shift in the amounts paid from the higher cost surgical procedures to primary care. This will help to create new incentives for physicians to enter and concentrate on providing primary care. We believe this is desirable because it will lead to more preventive medicine and will result in less need for later surgical intervention.

Although Congress has specified that physician payment reform should be implemented in a budget neutral fashion, we believe that in the long run there will be significant savings to the Medicare program due to the shift in emphasis to prevention and primary care.

Our FY 1991 budget includes a number of proposals designed to facilitate the movement to the resource based fee schedule for physicians that will go into effect in 1992. It also identifies and proposes corrections for a number of instances where there is currently excessive or duplicative payments.

Question. Should we be investing more in reviewing the payments for the highest cost care or changing the incentives for physicians and hospitals to treat patients in more cost effective ways?

Answer. There is a major problem in the way in which health care in this country is delivered and paid for. Top of the line care in America is the envy of the world. The "miracle" procedures, technology, and drugs available here enable us to provide a quality of care that is unexcelled. But these "miracles" are not inexpensive. We must insure that our use of new technology is done in a careful and prudent manner so that it does not squeeze out more fundamental forms of care.

But artificial or arbitrary constraints, in either the high cost items or the more basic services, will only discourage innovation and limit access, especially for the poor and minorities. The problem isn't a shortage of health care dollars. The problem is the lack of a rational system in the delivery and payment for care.

Because of the lack of coordination in our health care delivery system, our medical marvels exist side-by-side with millions of people who have little or no care. And even those who have access to care frequently find the cost burdensome. If we are to insure adequate care for everyone, we must find ways to bring greater coherence, coordination, and efficiency to health care delivery.

The prospective payment system and the new resource based scale for physician payments, in conjunction with our managed care initiatives contained in the FY 1991 budget, will make major changes in the incentive structure for health care delivery under Medicare and, we believe, will serve as a model for health care delivery for the remainder of the population.

But even these innovations will not address the problems of the uninsured or those in need of long term care. Therefore we eagerly await the recommendations of the Pepper Commission, the Steelman Advisory Council, and the Undersecretary's Work Group.

Question. What approaches do you believe hold the greatest promise for success?

Answer. Managed care offers the best hope of providing appropriate care while containing the spiraling cost of providing that care. By emphasizing primary care, early intervention, and comprehensive patient-oriented, rather than procedure-oriented, care, managed care will enhance the quality of the care provided. It will prevent the postponement of treatment that so often leads to life-threatening deterioration of health conditions that require emergency, traumatic and expensive corrective intervention.

By bringing order and system to the delivery of care, managed care will reduce excess and duplicative treatments and procedures. And to the extent that managed care incorporates capitation and risk-based payment plans, there is a strong inherent incentive for increased efficiency.

As I have mentioned, the FY 1991 budget includes several proposals to further our goal of the greater use of managed care. We propose to increase the payment to risk-based HMOs. The increase will be shared with the beneficiaries and thus serve as a dual purpose incentive for the creation of new HMOs and increased beneficiary participation. Our innovative Medicare Plus proposal also provides a new form of managed care which we believe will encourage greater participation while incorporating incentives for efficient delivery of care. In the Medicaid program, we will be offering financial incentives for states to make greater use of managed care for Medicaid recipients.

WELFARE HOTELS

Question. During last year's hearings, I pointed out that millions of AFDC/Emergency Assistance funds were being used to support "welfare hotels" that can cost $2,000 per month. We have now enacted $20 million to operate McKinney Act demonstration programs to reduce the number of AFDC families in welfare hotels.

What progress has been made to reduce the use of Emergency Assistance funds to house AFDC recipients in welfare hotels?

Answer. In July, 1989, HHS sent a report to Congress which contained recommendations on ways to reduce the use of Emergency Assistance funds to house AFDC recipients in welfare hotels.

One recommendation, supported by the Congress in Appropriations report language, was to revise current proposed regulations on the uses of Emergency Assistance funds. These revisions would restrict use of these funds to emergency needs incurred during any thirty consecutive days in a twelve month period, but would continue to allow their use to pay rent and utilities that have fallen in arrears, or to pay security deposits and first month's rent to move individuals into more permanent housing. These revised regulations are being drafted, and are expected to be published later this year.

HHS has also begun to collect data on the use of Emergency Assistance and AFDC special needs funds for housing in hotels and similar temporary housing arrangements. Such data collection is required by section 8005 of the Omnibus Budget Reconciliation Act of 1989.

HHS will also propose legislation this Spring to prohibit the use of AFDC and Emergency Assistance funds for welfare hotels, although short emergency stays in commercial facilities would be permitted.

Question. What States have been chosen to operate the McKinney Act demonstration programs, and when do you expect to see results?

Answer. At this time, no States have been chosen to operate the McKinney Act demonstration programs. A program announcement is being drafted and should be published by late Spring. Decisions will be made in the fourth quarter on the two to three States which will receive project awards. Project durations could then extend for up to 36 months before we expect final results to be available.

Question. Why was the Office of Human Development Services chosen to administer these demonstration projects, despite the fact Congress appropriated the funds to the Family Support Administration?

Answer. These funds will be administered by the Family Support Administration's Office of Community Services (OCS), not by the Office of Human Development Services (OHDS).

PEDIATRIC AIDS INITIATIVE

Question. Would you support targeting funds to Title X clinics for outreach, counseling and testing for HIV-positive women and others at risk for HIV infection, and to provide contraceptive services to these high-risk women?

Answer. We certainly agree that Title X clinics provide a good locus for the activities you mention. In fact, funds provided to these programs through the Family Planning Program have traditionally been used for outreach, counseling and testing for a broad array of services which have included diagnosis and treatment of sexually transmitted diseases (STDs), as well as for contraceptive services to high-risk and low income women. Although the 1991 Title X clinics budget does not contain any funds specifically targeted to HIV services for HIV-positive and high-risk women, we know that these services are provided with varying intensity, based on geographic incidence of infection, across the nation.

Also, these clinics seldom operate solely on federal Family Planning Program funds. In addition to State, local, and private resources, these clinics are eligible to apply for HIV/AIDS funds available through other agencies of the Public Health Service, including state CDC funds and grants from the Office of Minority Health.

AIDS PREVENTION ACTIVITIES

Question. Since 1989, we have spent over $1 billion on AIDS prevention activities. The FY 1991 budget requests a total of $421 million for this activity. What can you tell us about the effectiveness of these expenditures?

Answer. AIDS prevention/education activities do appear to be having a positive impact on changing behaviors that would place people at risk of HIV infection. We believe this may be one of the factors that could account for the apparent slowdown, since 1987, in the rate of increase of reported AIDS cases, particularly in homosexual men. Another measure of the effectiveness of AIDS prevention activities is that rates of syphilis in gay white males appear to have declined. For example, infectious syphilis rates for all white males in San Francisco decreased 90% between 1984 and 1989, from 250 to 25 cases per 100,000 population, reflecting safer sexual behavior among this population. Approximately 85% of white males with syphilis in San Francisco were gay or bisexual. Nationally, between 1982 and 1989, syphilis rates for all white males declined 68%, from 10.3 to 3.3 cases per 100,000 population. This decline has occurred despite a rising incidence of the disease in the heterosexual population. Also, rates of HIV seroconversions, or new infections, among participants in a cohort study in San Francisco have declined from 20% in 1982 to less than 2% in 1984, and have since remained constant at less than 2% per year.

Since HIV counseling and testing began in public sites in 1985, nearly 2.2 million tests are reported to have been performed and almost 137,000 of these have been reported as positive. Pre- and post-test counseling is a key prevention strategy for motivating and assisting people to change their high-risk behaviors and maintain low-risk ones. Results of 38 studies on HIV counseling and testing indicate that high-risk behaviors can be decreased through these intervention efforts. Six of these studies on IV drug users have shown decreases in risky injection practices. For example, Sacramento, California demonstrated a 23% decline in the proportion of IV drug users who continued sharing needles or using non-disinfected drug paraphernalia after participating in an AIDS education/testing program located in drug treatment centers between 1986 and 1988.

Furthermore, surveys indicate that general public awareness of AIDS issues has increased, and levels of misinformation about how the disease is and is not transmitted — a potential cause of discrimination — has declined since the PHS "America Responds to AIDS" campaign was initiated in 1987. Public demand for AIDS information continues to expand. The National AIDS Hotline currently receives an average of 2,800 calls a day, or 84,000 calls a month, for a total of 3,879,817 since 1987; and the National AIDS Clearinghouse is currently distributing over 1,000,000 documents each week.

It is still too soon for much more program effectiveness data to be available since a significant amount of CDC funds were not devoted to AIDS information/education projects until 1987, with $103 million, and 1988 with $209 million, compared to 1986 with $34 million. However, CDC continues to incorporate evaluation as a basic component of its AIDS activities. In 1989, program activities which constituted 94% of CDC's AIDS budget had evaluation activities in place or planned. Additional efforts are planned in the 1991 budget to evaluate the efficiency as well as the effectiveness of alternative prevention approaches, that is, which approach is "best"?. Specifically, in 1991, CDC plans to spend an additional $8.3 million to compare the effectiveness of alternative AIDS counseling techniques, such as peer vs. professional counseling, and to assess the effectiveness of street outreach and bleach distribution programs in reducing rates of HIV infection among IV drug users and their sex partners.

Question. Do you feel we have made significant progress in changing the attitudes that would lead to the prevention of the spread of AIDS?

Answer. As the above answer indicates, significant progress has been made in changing many people's attitudes toward behaviors that could place them at risk of AIDS and HIV infection. The recent news of declining HIV incidence in some groups, particularly gay men, is encouraging and indicates that public education does work, and that more people are listening to the message on avoiding AIDS and are changing their behaviors.

However, this decline is not uniform across all groups of high-risk populations, particularly minorities and IV drug abusers. A recent upturn of sexually transmitted diseases in the gay population of Seattle Washington suggests that AIDS prevention messages must be reiterated both for current and new members of the gay community. It is clear that further prevention efforts are still needed to ensure that our AIDS message reaches all Americans. Consequently, we are requesting an increase of $61 million in 1991, primarily in CDC, to expand our AIDS/HIV prevention and education efforts to over $425 million.

$15 MILLION EXTRAMURAL CONSTRUCTION PROGRAM

Question. Mr. Secretary, as you know, the Committee included $15 million for an extramural construction program to be managed by NIH. A number of projects were discussed by the Congress as being eligible and of interest by the Congress for funding under this limited program. These included projects in Maine, New Mexico, Montana, Mississippi, Georgia, and Colorado. Could you tell us the status of this program, and when will the awards be made?

Answer. On February 16, 1990, NIH will publish in its Guide to Grants and Contracts two requests for applications (RFAs) for extramural facilities construction projects. One RFA will announce the availability of up to $10 million for a mouse breeding facility to replace the capacity lost last year when a major laboratory facility was destroyed by fire. The second RFA will announce the availability of $3 million for general biomedical research facility construction. In addition, the National Cancer Institute will use $2 million of the 1990 extramural construction funds to support two previously approved applications for construction of cancer research centers.

NIDA OUTREACH TO DRUG ABUSERS

The FY 1991 budget proposes to cut funding for NIDA demonstrations over $18 million. The entire cut would come out of a program oF HIV/AIDS demonstrations, designed to find effective ways of recruiting IV drug abusers into treatment.

Question. What results have these demonstration projects shown? What are the most effective methods of getting IV users into treatment?

Answer. The AIDS/IV drug abuse demonstration projects were designed to demonstrate the effectiveness of various techniques for encouraging intravenous drug abusers into treatment and reducing behaviors which would increase their risk of HIV infection. Early assessment indicates that these demonstration projects have been worthwhile. The demonstrations showed: the importance of IV cocaine use in the spread of AIDS; that we can identify and educate the sexual partners of IV drug abusers; that expanded traditional heroin treatment programs (i.e., methadone) is not enough to combat cocaine abuse; and that there are a large number of people who have used drugs for many years who have never been in treatment. NIDA will be completing these projects during this fiscal year. Once the projects are completed, the results of these studies will be published and disseminated to the drug abuse treatment and prevention field.

Question. Given that substance abuse, especially IV drug abuse, accounts for the fastest growing segment of the HIV population, why have you chosen to discontinue these important projects?

Answer. The AIDS/IV drug abuse demonstration projects were designed to demonstrate the effectiveness of various techniques for encouraging intravenous drug abusers to enter treatment and that behaviors which would increase their risk of HIV infection can be reduced. We believe these demonstration projects have been worthwhile. While NIDA will no longer be funding demonstration projects in this area, we will still support research on the effectiveness of new and innovative outreach techniques. These studies will be supported with increases in our AIDS research program and will be more tightly controlled than the demonstration programs were. This approach is expected to increase the reliability of the information drawn from these studies and represents a second generation of studies in this area.

Question. What can you tell us about your commitments to mental health and alcohol abuse initiatives?

Answer. I remain strongly committed to helping individuals, families and communities address the complex issues related to mental illness and alcohol dependence. This commitment includes both improving scientific understanding of how to diagnose, prevent, and treat these disorders, as well as continuing to work with States and the private sector to improve service delivery.

The Department's request for the National Institute of Mental Health (NIMH) includes an increase of $28 million for research. We are committed to making the 1990s the "Decade of the Brain" in our pursuit of research on the brain, including schizophrenia, the most chronic and disabling of the major mental illnesses. Our 1991 request includes, among many initiatives, the funding of a new center for excellence in molecular neurobiology as called for in the National Plan for Schizophrenia Research.

The research component of the National Institute on Alcohol Abuse and Alcoholism increases by 5 percent. Under our proposal, NIAAA will have received a 31 percent increase between 1989 and 1991. In the service areas, the ADMS Block Grant will have received a 71 percent increase for alcohol abuse activities from 1989 to 1991.

AIDS - BLEACH DEMONSTRATIONS

Question. You have stated in the past that providing drug addicts with clean needles or other paraphernalia is unacceptable. But many drug addicts are on treatment waitlists or may not yet be seeking treatment. Considering the rapid spread of HIV and AIDS among this population and their sexual partners -- and the unfortunate children born to this population, what is your position on completing research demonstration projects currently underway that are providing bleach to IV drug abusers to assess its effectiveness in reducing the spread of AIDS and the HIV virus?

Answer. The Public Health Service does not oppose programs to distribute bleach as part of a comprehensive drug abuse outreach program. Since bleach is readily available legally, we view its distribution as only giving drug users the means to protect themselves and others from a fatal infection until they can be brought into treatment. Programs of this type, currently funded by HHS, have shown no evidence of having contributed to the spread of drug abuse. In 1991, CDC is requesting an increase of $4.1 million to evaluate the effectiveness of street outreach and bleach distribution programs in reducing HIV infection rates in IV drug abusers and in their sex partners.

MINORITY HEALTH INITIATIVE

Question. Is it your intent to give minority students freedom of choice in where they go to school, or should they attend only certain schools?

Answer. Our 1991 proposal places no restrictions on where students receive their educations. Health professions scholarship and loan opportunities will be available, not only through universities and colleges with high minority enrollment, but also to students applying for scholarships to attend any accredited institution, or program, of choice.

Question. And if you would allow students a choice, shouldn't the money follow these students?

Answer. Yes. Depending upon where they are accepted into health professions programs, students applying for financial assistance through HHS scholarship and loan programs will determine to which institutions these funds are directed.

Question. What incentives do you propose to offer all schools to increase their enrollment of minorities?

Answer. For schools with at least 25% of its students from disadvantaged backgrounds, we propose to make professional education enhancement grants to health professions schools to provide academic reinforcement and enhanced educational resources available to their students, while maintaining tuition rates at levels appropriate to the financial capabilities of the school's traditional student body. In addition, we propose to make faculty development grants to similar institutions to sponsor faculty post-doctoral training and biomedical research opportunities.

Question. Will the Administration propose legislation authorizing the programs funded under your minority health initiative?

Answer. While we believe we can do most of our initiatives under current authorities, in order to remove any doubt and strengthen our proposal, we are currently considering the possibility of proposing legislation in concert with the 1991 budget initiative to reaffirm, clarify, and slightly expand existing authorities.

Question. Could you summarize for us the differences between your minority health proposal and the legislation passed by the Congress last year, and discuss with us why your proposal has deviated for Congressional legislation?

Answer. We support the legislation drafted by the

Congress in principle and spirit, however, our proposal deviates from this legislation in certain specific ways. First, our proposal maintains Secretarial flexibility to establish Department priorities and distribute funds and program responsibilities accordingly.

The opportunity for loan and scholarship obligors to provide services in underserved areas in return for financial assistance is another important feature of our plan. We believe the benefits of such an arrangement include improved health status for populations served, economic benefits for these communities, and the possibility of long-term enhancement of access to health care for underserved populations. In fact, one of the scholarship programs we are proposing would permit community-based organizations to recruit persons for health professions training in exchange for providing health services to that community, hopefully beyond the scholarship payback period. We also support the Congressional proposal for health professions faculty to receive similar financial assistance payback opportunities.

We look forward to continuing to work cooperatively with the Committees in both the House and the Senate and other components of the Congress as legislation for disadvantaged and minority health is developed.

Question. Will you be offering any authorizing legislation?

Answer. As I stated earlier, we believe we can do most of our initiatives under current authorities. However, in order to remove any doubt and strengthen our proposal, we are currently considering the possibility of proposing legislation in concert with the 1991 budget initiative to reaffirm, clarify, and slightly expand existing authorities.

HEALTH PROMOTION AND DISEASE PREVENTION

Question. Less than one-half of one percent of the nation's health costs are spent on prevention -- far too little in my opinion. Not only does prevention serve our citizen's health needs better, but it greatly reduces soaring medical costs. What initiatives are included in your fiscal year 1991 budget request to strengthen health promotion and prevention activities?

Answer. We estimate that over $6 billion are included in the HHS 1991 budget request for prevention activities. This is an increase of over $454 million, or +8.2%, above the record high level in 1990. These funds will be used primarily for research, disease control, health promotion, and nutrition services. Examples of major prevention-related increases proposed in 1991 include a $70 million increase for ADAMHA substance abuse prevention activities; a $61 million increase for AIDS education/prevention projects, primarily in CDC; a $78 million increase for NIH prevention-related biomedical and behavioral research; a $84 million expansion in FDA product inspection and evaluation activities; and an estimated $54 million increase for nutrition and health services for children provided through Head Start programs. Also, Medicare expenditures for cervical cancer pap smears, mandated by the 1989 Omnibus Budget Reconciliation Act, are expected to grow to $40 million in 1991, a $30 million increase over 1990.

OFFICE OF THE GENERAL COUNSEL

Question. The FY 1991 budget requests an increase of $1.496 million for the Office of the General Counsel (OGC), but at the same time requests a cut of 25 FTE. Please explain the need for the increased funds and how the proposed staffing cut would affect operations of OGC.

Answer. The $1.496 million increase in FY 1991 is due in part to a one-time only transfer of $734,000 from the General Departmental Management (GDM) account to OGC, to correct an imbalance in the area of Rental Payments to GSA. The remaining $762,000 increase is necessary to cover built-in personnel costs related to pay raise annualization expenses, particularly the recently approved pay raises for Executive Level and SES personnel. Based on the current funding request, it is estimated that only 735 FTEs can be funded in FY 1991. OGC anticipates that most of this 25 FTE decrease will be absorbed through increased efficiency and automation, plus a potential decrease in the number of new cases filed against the Department in the Social Security Disability Litigation area. However, OGC will not be able to devote increased resources to enforcement activities, notably in the Health Care Financing, Inspector General, and Food and Drug Administration areas.

OFFICE FOR CIVIL RIGHTS

Question. The inventory of unresolved complaints at the beginning of FY 1989 totaled 558. At the beginning of FY 1990, the number had increased to 597. The proposed budget projects an inventory of 637 cases at the start of FY 1991. Given the increasing backlog, is the budget request for OCR adequate?

Answer. Although the absolute number of pending complaints is projected to increase during the next two fiscal years, the inventory will remain relatively constant as a proportion of the overall workload (from 25.4 percent in FY 1989 to 26.6 percent in FY 1991). In comparison, the inventory at the end of FY 1987 was 31.3 percent. OCR will continue its ongoing efforts to increase productivity through office automation and staff development. In addition, staffing allocations will be managed to assure that OCR maintains a balanced compliance program.

POLICY RESEARCH

Question. How are the findings of Policy Research studies disseminated?

Answer. The results of Policy Research studies are disseminated in several ways. First, all reports are submitted to the Department of Commerce's National Technical Information Service (NTIS), so that they will be available to the general public. Second, abstracts of research in progress and completed projects are published in compendiums on particular research areas, such as long-term care, poverty-related research, etc. These compendiums are widely disseminated. Third, research findings are shared through sponsored conferences and working sessions with researchers, policy-makers, etc. For example, last year Policy Research held a conference on research and the quality of long-term care. The most recent conference, held in January 1990, was on improving the collection of data on child support and alimony, in order to assist in assessing improvements in national child support collections. Finally, Policy Research itself disseminates full studies which contain important findings.

Question. What is the projected split in the FY 1991 budget between continuation contracts and new contracts?

Answer. Policy Research estimates that approximately 60 percent of the funds in its FY 1991 budget will be spent on new projects via contracts, grants, or interagency agreements. The remaining 40 percent of funds will be spent on continuing projects.

Question. What are the priority areas for new studies in FY 1991?

Answer. The studies planned for FY 1991 will address the following four priorities:

(1) strengthening the family, including self-sufficiency for low income families, families with special problems, the effectiveness of State dependency-reduction activities, child care issues, and the problems of "at risk" children;

(2) improving access to quality health care at a reasonable cost, including improving the delivery and quality of health care and addressing health care financing and cost issues, such as medical liability;

(3) improving the well-being of the elderly and disabled, including the financing and delivery of long-term care; and

(4) improving the delivery of human services and other forms of assistance, while encouraging personal responsibility.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

HEALTH PROFESSIONS

Question. In view of the fact that the FY 1991 budget proposes to cut $124 million in health professions, how do you plan to address this shortage in order to avert a crisis in our nation's health care delivery system?

Answer. I am committed to reducing the shortage of health professions and have focused on efforts on disadvantaged and minority students and programs which work toward providing health professionals in designated Health Manpower Shortage Areas.

The Administration's request includes $75 million for health professions programs which are targeted toward minority students, including $17 million for two new health professions programs which are part of our Minority Health Initiative.

As you know, the National Health Service Corps (NHSC) places health professionals in areas with shortages. The NHSC recruitment program, comprised of scholarships and loans, provides needy students the opportunity to receive a health professions education while receiving commitments from these students to serve in Health Manpower Shortage Areas. Therefore, our budget includes $42 million for existing members of the National Health Service Corps and $64 million for the National Health Services Corps Recruitment program. Of the $64 million, $55 million is part of our Minority Health Initiative.

Three major student assistant programs continue to exist: Health Professions Student Loan program, Nursing Student Loan program, and the Health Education Assistance Loan program. Although, we are phasing out the latter as we study better alternatives.

Question. How would the Administration's FY 1991 proposal for the NHSC impact on rural states like West Virginia?

Answer. The Administration's budget increase for the National Health Service Corps (NHSC) recruitment program is a step toward increasing the number of health professionals which will serve in rural areas. The Administration's proposal for the NHSC includes a $64 million increase for recruitment in the form of providing scholarships and loans to needy health professions students. In return, recipients of scholarships and loans make commitments to serve in Health Manpower Shortage Areas which includes many rural areas and States such as West Virginia.

Question. What is being done to recruit NHSC members to fill vacancies in West Virginia?

Answer. For West Virginia, the National Health Service Corps (NHSC) program has identified 6 high priority sites to be filled by obligated assignees, 3 loan repayment obligor sites, and 16 volunteer assignment sites to be recruited for during 1990. In addition, in 1989 West Virginia was the recipient of a State loan repayment grant award which funded 3 loan repayment agreements with practitioners in the State.

Almost every hospital in the nation reports difficulty in filling its nursing staff vacancies. Nurse recruitment is particularly difficult in rural areas. In the face of these shortages, you propose to reduce nursing education by $53 million.

Question. How do you plan to address this shortage?

Answer. Some of the latest information available suggests that there might be a slight easing of the nursing shortage, at least in some areas. The vacancy rate for registered nurses in hospitals has declined slightly between December of 1987 and 1988, from 11.3 percent to 10.6 percent, according to the latest data available from the American Hospital Association. First-time enrollments in basic nursing education programs have shown some increases, rising 4.3 percent to 94,594 in the 1987-1988 academic year over the total of 90,693 in 1986-1987; and indications are that first-time enrollment levels may show some increases in 1988-1989 as well.

The Commission on Nursing assessed the cause of the nursing shortage as stemming from the increases in employer demand. The March 1988 National Sample Survey of Registered Nurses reinforced such a conclusion. The survey showed that more nurses were employed than ever before — 1.6 million compared to 1.5 million found in the November 1984 sample survey. It also showed that a higher proportion (eighty percent) of all licensed registered nurses are employed in nursing than previously.

Our FY 1991 request does include $4 million for nurse training through our health professions program as well as $13 million available through the nursing student loan revolving fund. NIDA Outreach to Drug Abusers

The FY 1991 budget proposes to cut funding for NIDA demonstrations over $18 million. The entire cut would come out of a program oF HIV/AIDS demonstrations, designed to find effective ways of recruiting IV drug abusers into treatment.

OCCUPATIONAL SAFETY AND HEALTH LABORATORY CONSTRUCTION

Question. The FY 1990 appropriation provided $5 million for "high priority" construction to the Centers for Disease Control. The Centers for Disease Control plans to build a state-of-the-art occupational safety and health laboratory.

Please provide information on why a state-of-the-art occupational safety and health laboratory is required, a timetable for the construction of the facility, and the number and type of staffing required.

Answer. I have been informed by CDC that the $5 million add-on provided by Congress in 1990 for "high priority" construction projects will be used to update design plans for a new occupational safety and health laboratory at the NIOSH facilities in Morgantown, West Virginia. CDC currently estimates that the construction cost of a 150,000 gross square foot building would be approximately $29 million. A facility of this size could house about 310 scientists and support staff. The design work begun in 1990 is expected to be completed in 1992. Major construction projects of this type generally require 18 to 36 months to complete and become operational once the construction contract has been awarded. There are no funds included in the 1991 President's budget for construction of this facility. I expect that the relative priority of this facility will be reviewed during the Department's 1992 budget process.

SOCIAL SECURITY ADMINISTRATION

Question. Please provide a list of Social Security offices in West Virginia.

Answer. The Social Security Administration has 17 district and branch offices located in West Virginia. They are:

- Beckley
  214 N. Kanawha St., P.O. Box Y 25801
- Bluefield
  3425 E. Cumberland Rd. 24701
- Charleston
  1206 Quarrier St., P.O. Box 1788 25326
- Clarksburg
  722 W. Pike St., P.O. Box 1610 26301
- Elkins
  300 3rd St., P.O. Box 1086 26241
- Fairmont
  1000 Fairmont Ave., P.O. Box 2710 26555
- Huntington
  Rm. 207, 640 Fourth Ave. 25701
- Logan
  511 Dingess St. 25601

- Martinsburg
  4th Floor, 225 W. King St., P.O. Box 1597 25401
- Montgomery
  307 Adams St., P.O. Box 809 25136
- Morgantown
  Mountaineer Mall, Greenbag Rd., P.O. Box 870 26507
- Parkersburg
  963 Market St., P.O. Box 1947 26101
- Petersburg
  439 Keyser Ave. 26847
- St. Albans
  505 6th Ave., P.O. Box 759 25177
- Welch
  275 Virginia Ave., P.O. Box 669 24801
- Wheeling
  50 16th St. 26003
- Williamson
  50 W. 2nd Ave., P.O. Box 1580 25661

In addition, some residents of West Virginia are served by Social Security offices located in Covington, Virginia; Harrisonburg, Virginia; Cumberland, Maryland; East Liverpool, Ohio; and Steubenville, Ohio.

Question. Are there any plans to close any of these offices or to reduce staffing in either FY 1990 or FY 1991?

Answer. SSA has no plans to close any of these offices, and the staffing level in the state of West Virginia is expected to remain stable in FY 1990 and FY 1991.

QUESTIONS SUBMITTED BY SENATOR WARREN B. RUDMAN

LOW INCOME HOME ENERGY ASSISTANCE

Question. Your justification cites the "temporary nature" of the LIHEAP program at the time it was created as justification for continuing the decrease in funding. Would you consider freezing to death because of an inability to afford heat a temporary condition?

Answer. We do not believe the Federal Government has the sole responsibility for providing heating assistance to low-income persons. Because of the variation in energy assistance needs, individual States could be taking a more expansive role in meeting the energy needs in their respective jurisdictions. We would further note that under our budget proposal, eligible households would have lower average out-of-pocket heating costs than in the early and mid 1980's (adjusted for inflation).

Question. How many Governors have written the President asking for consideration of a supplemental appropriation?

Answer. Seventeen Governors signed a letter dated January 8, 1990 to the President seeking additional LIHEAP funding. Some of these States also divert LIHEAP funds to other programs.

Question. Your budget justification indicates that in fiscal year 1989, the LIHEAP program assisted 5.5 million eligible households, less than one-third of the 17.9 million eligible households. How many fewer households will be assisted under your fiscal year 1991 proposal?

Answer. Because LIHEAP is a block grant which affords the grantees flexibility in designing their energy assistance programs, there is no direct correlation between reductions in Federal appropriations and households served. Thus, we are unable to estimate the number of households served at any level of Federal appropriations. LIHEAP grantees may supplement their Federal appropriation with State or oil overcharge monies, States could transfer funds into LIHEAP (up to $292 million in FY 1990), and stop transferring funds out of LIHEAP into other block grants, eliminate a services component such as cooling or weatherization or reduce the size of the benefit provided.

Question. The average benefit per assisted household was $202 in fiscal year 1989. What effect will the cut have on the average benefit of an eligible household?

Answer. As with the number of households served, we are unable to estimate the impact on benefit levels since State's have great flexibility in administering their LIHEAP program. Further, the data that we collect from the States is from a voluntary survey conducted by FSA staff twice a year.

Question. Mr. Secretary, it is my understanding that your Department recently surveyed a sample of States to determine if their LIHEAP resources were sufficient to meet this year's unusual energy needs. It is my further understanding that the survey found that no States had actually closed their energy assistance program.

Did the survey also ask how many eligible households had exhausted their benefits or whether programs had implemented reductions in benefits or in eligibility standards to conserve resources? If so, what did the survey find? If not, are you guilty of failing to ask the whole question?

Answer. The Family Support Administration is in the process of compiling the data from their winter survey which was conducted in mid-January. They expect this information to be ready for dissemination by the end of March. At the end of January, a very brief, informal survey was conducted in which FSA asked some of the States most impacted by the cold weather, if they had utilized all of their LIHEAP funds and if they intended to request additional funds. In order to determine how many eligible households had exhausted their benefits would require extensive time-consuming efforts by the States. This most recent spontaneous survey did not cover the detail of questions asked in the normal bi-annual survey.

Question. How many States identified the OMB's apportionment rules as being part of the problem?

Answer. The Administration has received five requests from Governors seeking the full grant award prior to the third quarter of fiscal year 1990. These include: Maine, New Hampshire, Vermont, Iowa and Massachusetts.

Your budget justifies the proposed LIHEAP cut of $343 million in FY 1991 by citing the fact that 29 States currently transfer funding from LIHEAP to other block grant programs. While I would note that such transfers are permitted under law, I would also note that many of the States represented on this Subcommittee do not take advantage of this authority, including — New Hampshire, Iowa, Pennsylvania, Alaska, South Carolina, Mississippi, and Hawaii.

Question. Would you support a change in the authorization to prohibit transfers from the LIHEAP program?

Answer. The legislative proposal submitted by the Administration would permit States that had not exercised the option to transfer funds from the LIHEAP program to receive the entire annual grant award prior to the third quarter. State transfer of funds between block grants clearly indicates what States perceive their needs to be.

Question. Should the program be changed to better target energy assistance toward those States most in need of such assistance?

Answer. The formula for allocating the LIHEAP funds is contained in section 2604 of Public Law 97-35. This statutorily based formula has not been modified since fiscal year 1986, when the LIHEAP appropriation was $2.1 billion. Before there are any changes to the distributional formula Congress would need to assess the broad variation in energy assistance needs among the States. Neither the authorization nor appropriation language allows variation from the allocation formula when a few States experience unusual conditions.

The Administration has proposed amending the LIHEAP statute to permit States under certain circumstances to fully draw down LIHEAP allocations prior to March 15, 1990. OMB has interpreted this section to mean that 10% of a State's grant shall be reserved until after March 15; however, in the past OMB has waived this rule. In fact, in mid-January Family Support Administration officials were advising that States which had exhausted their initial LIHEAP allocations should request a waiver of the 90% rule, indicating that all requested waivers had been granted.

Question. On its face, the Administration's proposal recognizes a crisis situation. Why is a one time legislative change necessary when the statute places requirements on the States, not the Department and when waivers have been granted administratively?

Answer. On Friday, February 2, HHS sent a reapportionment request to OMB asking to make available for obligation funds held in reserve for award during the third quarter of fiscal year 1990. Subsequently, on February 5 the Administration suggested legislative modifications to the current statute which requires States to defer from obligations until march 15 of each year a reserve of funds to meet crisis. As of February 13, the OMB has apportioned $6 million of additional funds for 3 States: Maine, New Hampshire, and Iowa. These States had unusual conditions including excess cold weather together with a surge in prices for fuels used heavily in that State, and had fully dedicated the State's LIHEAP funds for energy assistance. At that time, not other Governors of States meeting these criteria had requested accelerated funding.

Question. Was the Department consulted on this legislation and did you participate in the development of the proposal?

Answer. The Department was not consulted prior to the submission of the Administration's legislative proposal.

Question. How many and which States will be assisted by the proposed statutory change?

Answer. We do not have this information at this time.

Question. Will this legislation solve the problem or is an emergency supplemental what this program really needs?

Answer. The legislation is intended to assist those States which experienced unusual circumstances resulting from the cold weather in Northern States this past December. We do not believe a supplemental is needed. Warm weather in January made up for cold weather in December. The National weather service predicts an average October to April heating season.

Less than a quarter of LIHEAP-eligible households were affected by temporary increases in fuel oil and propane prices.

MEDICARE SAVINGS

The FY 1991 budget achieves a $1.5 billion savings in Medicare outlays by accelerating the payment of Medicare claims through a regulatory process, thereby shifting payments which would have occurred in FY 91 to FY 90. This is contrary to policy initially established by the 1987 Budget Reconciliation Act which prohibited the payment of Medicare claims for 14 days after receipt of the claim and violates OMB's won policy guidelines for payment of claims. The 14-day holding period was established to provide financial accountability in the program.

OMB Director Darman has pointed out that the statutory basis for administratively accelerating these payment occurred as a result of a three-month gap in legislative prohibitions against administratively implementing Medicare cost savings in excess of $50 million. I would venture that the speed at which HHS implemented this regulatory change is unprecedented in the history of the agency.

Question. Where did this proposal originate? Did it come from HHS or was it developed by OMB?

Answer. This proposal originated during the formulation of the President's Budget. Both the Department and OMB had a hand in developing the proposal.

Question. How would the Medicare budget be affected if Congress should disapprove this shift in funds? Would the $1.5 billion loss result in an added burden on the beneficiaries, providers and carriers, who are already experiencing the results of overall cutbacks as a result of budgetary constraints?

Answer. The Medicare budget would have $1.4 billion more in outlays in FY 1991 that are now projected if this acceleration of payments is disapproved. Likewise, FY 1990 will have $1.4 billion less in outlays. Currently, Medicare contractors are maintaining a 14-day floor. Disapproval would have a slight adverse effect on providers, because it would slow the receipt of their payments in the interim period. Beneficiaries may be slightly affected by slower payments.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

JOB CREATION DEMONSTRATION

Question. Section 505 of the 1988 Family Security Act authorized a three year job creation demonstration which will use community development corporations to promote job opportunities for those on public assistance. The Fiscal Year 1990 budget year appropriation bill provided some $10 million for Family Support Administration research and evaluations. the conference report accompanying the bill identified the job creation demonstration as one of the activities to be funded. A number of members of the Senate, including myself, have written to the Secretary urging that this demonstration be fully implemented.

Please provide the Committee with a complete status report on the demonstration including its placement within FSA, the amount of funds that will be allocated to it, the number of grants to be made and the schedule for implementation.

Answer. Section 505 demonstrations will be administered by the Office of Community Services (OCS) in the Family Support Administration (FSA) beginning in FY 1990. A total of $3.5 million will be available in FY 1990 for these projects. The number of demonstrations funded will be based on the number and quality of the applications submitted. A program announcement is currently being developed, and funds will be awarded by the fourth quarter of this fiscal year.

COMMUNITY ECONOMIC DEVELOPMENT PROGRAM

Question. It is my understanding that the Community Economic Development program funded out of the CSBG discretionary fund is the only Federal program which targets economic development efforts by community development corporations working in poor communities. What is the rationale for terminating this program in FY 1991?

Answer. There are other Federal programs which provide similar services to those in the Community Economic Development program, e.g., the Minority Business Development Agency in the Department of Commerce and Small Business Administration loan programs.

QUESTIONS SUBMITTED BY SENATOR BOB GRAHAM

STATE LEGALIZATION IMPACT ASSISTANCE

Question. Does the Administration's FY 91 SLIAG proposal eliminate the FY 92 SLIAG appropriation provided for in Public Law 101-166?

Answer. Yes. The Department's FY 1991 SLIAG budget proposes to eliminate the funds Congress moved from FY 1990 to FY 1992.

Question. Does the Administration's language eliminate the "carry forward" authority of unused FY 1991 funds as provided for in the authorizing statute, the Immigration Reform and Control Act of 1989 (Sec. 204(b) (4))?

Answer. No. The proposed language does not affect any funds already granted to States. We do not eliminate the "carry forward" authority of unused FY 1991 funds in our proposed appropriation language.

Question. Does the Administration's language eliminate the return of any unused FY 1991 Federal offset funds to the States as provided for in the authorizing statute (Sec. 204 (a)(2)(D))?

Answer. The Department's FY 1991 budget appropriates $302,597 for the State Legalization Impact Assistance Grants Program, regardless of Federal offset estimates.

Question. It appears that the Administration's primary justification for reducing the FY 1991 appropriation and eliminating the FY 1992 appropriation is the low draw down rate by the States and low costs. How has the Administration taken into consideration that SLIAG was designed to be a reimbursement program and that there is a considerable lag between the time costs are incurred by local governments and the time they are billed to the Federal Government?

Answer. The combination of requested funding, low costs, and carryover balances will fund the services needed to assist legalized aliens as they assimilate into society. Congress clearly stated in IRCA that these funds are "to offset some of the costs incurred by State and local governments" in providing certain public assistance, public health assistance and educational services. By the end of 1991, most of these aliens will have been living and working in the United States for ten years.

Question. In the Administration's justifications to the Appropriations Committee, the following statement is made: "Data available to us so far indicates that newly legalized of the general population." This statement implies that the Administration does not yet have sufficient data on SLIAG costs. Does this statement indicate that additional data may become available that will demonstrate additional costs not anticipated in the Administration's request?

Answer. As in all program areas, the budgeting process is based on estimates of projected costs. Four years since Congress' original estimate of $4 billion, our projections for this program are more accurate. Based on actual costs submitted by the States, State estimates, draw down rates and an additional $1 billion States can expect to have as a result of much lower Medicaid costs than originally anticipated, we believe there are enough Federal funds to offset the costs experienced by States in serving the newly legalized aliens.

Question. Does the Administration have a State estimate of services liabilities accrued, but not yet billed and paid?

Answer. The Department has received State plans, estimates, and some actual costs.

Question. What is the factual basis for the Administration's statement that "Aliens legalized under the Immigration Reform and Control Act of 1986 (IRCA) have proven to be much more resourceful and self-sufficient than Congress and the Executive Branch had expected?" Please provide a detailed state by state analysis.

Answer. The States of California and Maryland, as well as the INS conducted surveys of aliens applying for legal status which indicated that this population has a high rate of employment and are not accessing public assistance programs. Aliens were not eligible for legalization if they were likely to become "public charges." Thus, legalized aliens are taxpayers, contributing directly and indirectly to State and local revenues.

Question. What is the "draw down rate" for each State to date?

Answer. The information follows:

Last Update 2/1/90

DRAWDOWN REPORT FOR FY 1988 SLIAG GRANT
as of 12/31/89

STATE	CUMULATIVE ALLOTMENT	TOTAL DRAWNDOWN	% DRAWNDOWN	UNDRAWN BALANCE
Arizona	$18,286,215	$1,003,643	5.5%	$17,282,572
Arkansas	$304,119	$66,165	21.8%	$237,954
California	$570,408,016	$189,326,264	33.2%	$381,081,752
Colorado	$6,393,299	$1,060,381	16.6%	$5,332,918
Connecticut	$1,141,629	$752,000	65.9%	$389,629
District of Columbia	$2,300,081	$212,747	9.2%	$2,087,334
Florida	$73,341,086	$3,777,600	5.2%	$69,563,486
Georgia	$3,315,344	$555,229	16.7%	$2,760,115
Hawaii	$698,141	$303,322	43.4%	$394,819
Idaho	$2,741,079	$797,544	29.1%	$1,943,535
Illinois	$32,470,320	$24,759,028	76.3%	$7,711,292
Indiana	$477,206	$403,500	84.6%	$73,706
Iowa	$283,626	$85,567	30.2%	$198,059
Kansas	$1,247,960	$1,247,960	100.0%	$0
Louisiana	$804,604	$18,351	2.3%	$786,253
Maryland	$2,608,991	$900,000	34.5%	$1,708,991
Massachusetts	$5,450,683	$4,713,008	86.5%	$737,675
Michigan	$1,074,082	$109,517	10.2%	$964,565
Minnesota	$491,293	$42,945	8.7%	$448,348
Missouri	$644,538	$368,124	57.1%	$276,414
Nebraska	$414,480	$136,737	33.0%	$277,743
Nevada	$3,751,016	$1,808,091	48.2%	$1,942,925
New Hampshire	$65,232	$9,308	14.3%	$55,924
New Jersey	$6,827,372	$673,819	9.9%	$6,153,553
New Mexico	$9,459,277	$996,948	10.5%	$8,462,329
New York	$41,908,998	$4,965,000	11.8%	$36,943,998
North Carolina	$2,192,094	$388,916	17.7%	$1,803,178
Ohio	$606,308	$0	0.0%	$606,308
Oklahoma	$3,371,333	$1,051,404	31.2%	$2,319,929
Oregon	$7,529,887	$4,626,374	61.4%	$2,903,513
Pennsylvania	$1,812,200	$654,739	36.1%	$1,157,461
Puerto Rico	$1,112,712	$0	0.0%	$1,112,712
Rhode Island	$1,411,597	$380,000	26.9%	$1,031,597
South Carolina	$443,176	$275,703	62.2%	$167,473
Tennessee	$624,140	$78,555	12.6%	$545,585
Texas	$102,758,454	$25,673,535	25.0%	$77,084,919
Utah	$1,821,650	$1,438,041	78.9%	$383,609
Virginia	$4,178,360	$598,278	14.3%	$3,580,082
Washington	$11,895,918	$2,447,420	20.6%	$9,448,498
West Virginia	$88,313	$0	0.0%	$88,313
Wisconsin	$1,012,434	$405,692	40.1%	$606,742
Wyoming	$732,737	$213,628	29.2%	$519,109
TOTALS	$928,500,000	$277,325,083	29.9%	$651,174,917

Last Update 2/1/90

DRAWDOWN REPORT FOR FY 1989 SLIAG GRANT
as of 12/31/89

STATE	CUMULATIVE ALLOTMENT	TOTAL DRAWNDOWN	% DRAWNDOWN	UNDRAWN BALANCE
Arizona	$20,779,799	$3,581,055	17.2%	$17,198,744
Arkansas	$688,593	$0	0.0%	$688,593
California	$522,456,754	$84,238,187	16.1%	$438,218,567
Colorado	$7,515,680	$3,543,461	47.1%	$3,972,219
Connecticut	$600,309	$0	0.0%	$600,309
District of Columbia	$2,290,968	$902,694	39.4%	$1,388,274
Florida	$69,671,262	$0	0.0%	$69,671,262
Georgia	$6,132,802	$36,337	0.6%	$6,096,465
Hawaii	$549,696	$0	0.0%	$549,696
Idaho	$2,930,717	$14,000	0.5%	$2,916,717
Illinois	$43,356,753	$14,825,519	34.2%	$28,531,234
Indiana	$725,437	$0	0.0%	$725,437
Iowa	$301,006	$0	0.0%	$301,006
Kansas	$1,412,088	$706,746	50.0%	$705,342
Louisiana	$583,017	$15,075	2.6%	$567,942
Maryland	$1,489,401	$0	0.0%	$1,489,401
Massachusetts	$4,962,902	$0	0.0%	$4,962,902
Michigan	$1,629,122	$0	0.0%	$1,629,122
Minnesota	$424,273	$0	0.0%	$424,273
Missouri	$644,918	$0	0.0%	$644,918
Nebraska	$376,944	$0	0.0%	$376,944
Nevada	$4,698,031	$997,295	21.2%	$3,700,736
New Hampshire	$127,597	$45,413	35.6%	$82,184
New Jersey	$8,243,441	$0	0.0%	$8,243,441
New Mexico	$7,557,796	$5,110,786	67.6%	$2,447,010
New York	$47,577,243	$90,000	0.2%	$47,487,243
North Carolina	$3,501,725	$0	0.0%	$3,501,725
Ohio	$688,280	$0	0.0%	$688,280
Oklahoma	$3,563,460	$0	0.0%	$3,563,460
Oregon	$6,677,232	$1,211,115	18.1%	$5,466,117
Pennsylvania	$2,035,635	$112,500	5.5%	$1,923,135
Puerto Rico	$1,783,799	$0	0.0%	$1,783,799
Rhode Island	$564,671	$50,000	8.9%	$514,671
South Carolina	$819,753	$0	0.0%	$819,753
Tennessee	$599,147	$0	0.0%	$599,147
Texas	$104,223,456	$52,079,253	50.0%	$52,144,203
Utah	$1,318,844	$0	0.0%	$1,318,844
Virginia	$5,194,736	$0	0.0%	$5,194,736
Washington	$7,927,322	$0	0.0%	$7,927,322
West Virginia	$86,086	$0	0.0%	$86,086
Wisconsin	$1,428,547	$67,466	4.7%	$1,361,081
Wyoming	$360,758	$0	0.0%	$360,758
TOTALS	$898,500,000	$167,626,901	18.66%	$730,873,099

Question. It is my understanding that ESL classes for eligible legalized aliens are generally filled to capacity. Please provide a detailed State by State justification of the Administration's contention that costs for English language and citizenship instruction are much lower than expected.

Answer. It is the Department's evaluation that when the legalization program has been completed, States are expected to have spent less than $300 million on required educational classes, roughly 12 percent of past and proposed grants to States. About 1 million of the ELA's would need the 60 required hours of instruction. The average rates States charge for instruction is below $5 per hour. From this, we estimate States will spend approximately $300 for required educational classes.

Question. Public Law 101-238 authorizes two additional uses of SLIAG funds -- for outreach activities and to prevent employment discrimination. Does the Administration anticipate an increase in costs billed as a result of this change in the authorizing statute?

Answer. The amount of SLIAG funds that may be used for these activities ranges between $2.4 million to $3.5 million in total. The use of SLIAG funds for each of these purposes is limited to 1 percent of each State allotment for years subsequent to FY 1988 or $100,000, whichever is greater.

Question. Did the Administration consider these additional activities in calculating its FY91 SLIAG request?

Answer. The Administration request would give States enough funds to double FY 89 spending levels for fiscal years 1990, 1991, and 1992.

QUESTIONS SUBMITTED BY SENATOR FRANK LAUTENBERG

SMOKING

Question. Do you support minimum age laws at the state level for the sale of tobacco products to minors?

Answer. Cigarette smoking is the leading cause of preventable death and yet the extent of its availability is appallingly great. For those 44 States that have banned the sale of tobacco products to minors, I commend them. I encourage all States and localities to enforce existing laws and to adopt stricter laws where necessary.

Question. Do you agree that the Federal government should encourage States without these laws to enact them?

Answer. In view of the lethal nature of tobacco and its easy accessibility to our youth, I encourage States to adopt and enforce strong laws against the sale and promotion of tobacco products to minors.

Question. Do you agree that 18 is a reasonable minimum age for States to enact?

Answer. The Federal government has historically deferred to the States to establish the age of majority and associated privileges. To a great extent, this limits Federal action. I believe, morally, that it is simply wrong to promote a product which, when used exactly as intended, causes death. It is especially reprehensible to lure young prople into smoking and nicotine addiction or to facilitate their purchase of tobacco products. Therefore, I think it is important to continue to encourage States and localities to enforce existing laws and to adopt stricter laws where necessary.

Question. Do you agree that the Federal government could be more helpful in helping States enforce minimum age laws?

Answer. I believe we must continue to encourage States to establish - and vigorously enforce - policies to protect minors from the harmful effects of smoking. For my part, I intend to use existing authorities and the influence of my office to continuously raise the issue of tobacco use and its adverse health effects. I also believe that the private sector can assist in the dissuasion of cigarette smoking, for example, by writing letters to tobacco retailers, requesting that they take aggressive action to prevent the illegal sale of tobacco to minors.

Question. What is your position on vending machine sales of tobacco products?

Answer. Bearing in mind that tobacco, itself, is a lethal product, I applaud actions by the States, such as Utah, Idaho, Maine, Alaska and New Hampshire which have restricted cigarette vending machine sales to locations inaccessible to minors. The town of White Bear Lake, Minnesota, has even gone so far as to ban cigarette vending machines entirely. I commend these jurisdictions for their leadership and urge others to take similar action.

Question. Should we permit tobacco products to be sold in vending machines?

Answer. To permit tobacco to be sold in unsupervised vending machines, or to send tobacco products through the mail, or to pass-out tobacco products freely without regard to age is most questionable, and such policies should be reviewed. After all, alcoholic beverages are not sold through vending machines.

Question. Do you agree that restrictions on vending machines are necessary in order for minimum age laws to be adequately enforced?

Answer. The availability of tobacco products to our youth is too easy and I think that strong action should be taken to prevent it. I encourage States to adopt and enforce strong laws against selling and promoting tobacco to minors.

Question. Do you agree that limiting vending machine sales of tobacco products to places where minors are not permitted would be one effective way of limiting youth access to tobacco products?

Answer. I believe these actions make sense - given that many cigarette vending machines are easily accessible to minors and allow circumvention of the laws that exist in 44 States banning the sale of tobacco products to minors.

Question. Do you support efforts at the state level which require schools to be smoke-free?

Answer. We need to promote a tobacco-free environment everywhere. This is particularly true in places predominantly occupied by our children - in day care and schools - so that they are not exposed to smoke-enclosed rooms nor to role models who use tobacco.

Question. Do you think the Federal government has a role to play in encouraging States to enact and enforce laws requiring that schools be smoke-free?

Answer. I think we need to prevent those actions in our society that influence children and young adults into starting to use tobacco. Protecting our young population is the responsibility of both the public and private sectors. To this end, I believe, strategies that help to establish and enforce policies to protect our minors from the lethal perils of smoking need to be encouraged.

Question. Do you think teachers should be able to smoke in schools?

Answer. Developing and implementing a successful nationwide anti-smoking strategy demands the participation and commitment of each of us. To get this message to our children, we must be consistent in our delivery of the message. We must de-glamorize tobacco use, minimize its social acceptability, underscore its lethal potential and lessen the exposure/visibility of role models who use tobacco.

AIDS HEALTH CARE

Question. What is the Department of Health and Human Services doing to address the high cost of AIDS care in cities like Newark and Jersey City?

Answer. With regard to HHS financing of direct health care for AIDS patients, the Federal Medicaid and Medicare programs are involved in paying for AIDS treatment where the patients qualify based on need. Nationally, about 40% of all AIDS patients have their care paid for through Medicaid. The estimated $870 million in total Federal Medicaid payments in 1991, plus the approximately $870 million in State matching funds, are expected to account for nearly 25% of total national AIDS medical costs. Many private insurers and all State Medicaid programs now include coverage for some HIV treatment drugs, such as AZT.

New Jersey was also the first State to apply for and be granted a Medicaid Home and Community Based Waiver to allow reimbursement for home treatment services to beneficiaries with AIDS and AIDS-related complex. Under this waiver, which became effective March 1, 1987, New Jersey is allowed to provide case management, personal care, medical day care, narcotic and drug abuse treatment, private duty nursing care, and intensive foster care to these beneficiaries. Through this waiver, New Jersey expects to be able to treat qualifying AIDS patients more humanely and at less cost than would be the case under standard Medicaid coverage for institutional services.

For the longer term, two principal efforts of HHS to address the high cost of AIDS care in States such as New Jersey are through research and prevention. Ultimately, finding treatments and vaccines against AIDS, and supporting information and education activities to prevent the spread of AIDS by changing high risk behaviors, will be the best defense against the high cost of AIDS care. In total, the Public Health Service (PHS) expects to spend almost $1.7 billion on AIDS/HIV research and prevention activities in 1991, an increase of $109 million, or +7%, over expected 1990 spending, and $395 million over 1989. AIDS/HIV prevention/education and surveillance projects supported by the Centers for Disease Control (CDC) in the State of New Jersey totaled about $8.2 million in 1989. This included, as examples, an AIDS education project with the Boys' and Girls' Club of Newark, which was provided about $109,000; a study with the City of Newark on the prevalence of tuberculosis among deceased intravenous drug users who were HIV-positive compared to those without HIV infection was funded for about $213,000; an AIDS prevention project with Planned Parenthood of Essex County was provided about $175,000; and information/ education projects with the Newark school system was provided about $180,000.

SUBCOMMITTEE RECESS

Senator **Harkin**. Thank you very much. The subcommittee will stand in recess until 1:15 p.m. At that time we will hear from the Family Support Administration, the Office of Human Development Services, the HHS Inspector General, the Health Care Financing Administration, and the Social Security Administration.

[Whereupon, at 12:30 p.m., Wednesday, February 7, the subcommittee was recessed, to reconvene at 1:15 p.m., the same day.]

(AFTERNOON SESSION, 1:18 P.M., WEDNESDAY, FEBRUARY 7, 1990)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FAMILY SUPPORT ADMINISTRATION

STATEMENT OF EUNICE S. THOMAS, ACTING ASSISTANT SECRETARY

ACCOMPANIED BY MICHAEL L. STURMAN, ASSOCIATE ADMINISTRATOR FOR FINANCIAL MANAGEMENT

OFFICE OF HUMAN DEVELOPMENT SERVICES

STATEMENT OF MARY SHEILA GALL, ASSISTANT SECRETARY

ACCOMPANIED BY ROBERT STOVENOUR, DIRECTOR, OFFICE OF MANAGEMENT SERVICES

OPENING REMARKS

Senator HARKIN. The subcommittee will come to order. We will start where we left off and do the Family Support Administration, followed by the Office of Human Development Services and then the HHS Inspector General. We will then proceed to the Health Care Financing Administration and the Social Security Administration.

We have a lot of ground to cover this afternoon. So, I hope we can all be brief and to the point. I would ask that the statements not be read but summarized and that two or three or four points be made, whatever you think is most important for us to consider.

We will hear testimony first from Eunice Thomas, Acting Assistant Secretary of the Family Support Administration, and then next we will hear from Mary Gall, Assistant Secretary for Human Development Services.

Welcome both. Your statements will be made a part of the record in their entirety.

And I ask you to please proceed, Eunice.

SUMMARY STATEMENT

Ms. THOMAS. Thank you, Mr. Chairman.

Mr. Chairman and members of the committee, I am pleased to be here today to talk about the fiscal year 1991 Family Support Administration [FSA] budget.

I would like to summarize briefly the priorities of the Family Support Administration's budget and President Bush's budget. These include continuing to maintain support for the Aid to Families with Dependent Children [AFDC] and Child Support Enforcement [CSE] Programs, and implementation of the welfare reform provisions included in the Family Support Act of 1988.

We continue to emphasize the protection of those most in need as a priority. Under the AFDC program, full funding will maintain benefits to approximately 3.9 million families. At the same time, our investment of $1.2 billion in child support enforcement will lead to $6.8 billion of collections from absent parents, an increase from estimated 1990 collections of over $900 million. More than $2 billion will be collected on behalf of AFDC families, thereby providing needy families with greater economic self-sufficiency and lowering the amount of Federal and State funds needed to meet the cost of providing assistance.

Implementation of the Family Support Act of 1988 continues to be one of our highest priorities. By October 1, 1990, all States are required to make the transition to the new education, employment, and training program for welfare recipients. This program includes reimbursement for child care and other work-related expenses, as well as extended child care and Medicaid benefits when an individual leaves the AFDC roles due to work; 27 States already have their programs in place. We are requesting the full $1 billion program authorization for fiscal year 1991.

A key element for effective implementation of this legislation is a close working relationship with the Departments of Labor and Education. In this context, I am pleased to tell you that in November 1989 a 3-year technical assistance effort to assist States and Indian tribes was jointly announced by the three Departmental Secretaries. We will urge similar coordination at State and local levels to prevent duplication and maximize the use of available resources.

Finally, we have proposed funding levels for our programs that reflect Gramm-Rudman-Hollings objectives while pursuing our overall domestic spending priorities.

PREPARED STATEMENT

In closing, let me say that this budget reflects our commitment to supporting America's families through vigorous implementation of the Family Support Act, as well as aggressive enforcement of parental responsibilities for their children's economic well-being. We believe we have struck a balance between prudently managing our scare resources and identifying opportunities for reducing Federal spending.

Senator HARKIN. Thank you very much, Ms. Thomas.

[The statement follows:]

STATEMENT OF EUNICE S. THOMAS

I am pleased to be here today to talk about the fiscal year 1991 Family Support Administration (FSA) budget.

I would like to summarize the FSA priorities which are presented in President Bush's budget. These include continued support for the Aid to Families with Dependent Children (AFDC) and Child Support Enforcement (CSE) programs, and implementation of the welfare reform provisions included in the Family Support Act of 1988.

- Our request is designed to protect those in need. Under the AFDC program, full funding will maintain benefits to approximately 3.9 million families. At the same time, our investment of $1.2 billion in child support enforcement will lead to $6.8 billion of collections from non-custodial parents. This represents an increase from estimated 1990 collections of over $900 million, or 16 percent. More than $[illegible] billion will be collected on behalf of AFDC families. This money provides needy families with greater economic self-sufficiency, assures the financial responsibility of natural parents toward their children, helps to forestall welfare dependency, and offsets part of the cost of public assistance.

- Implementation of the Family Support Act of 1988 continues to be one of our highest priorities. To date, 27 states have made the transition to the new Job Opportunities and Basic Skills Training (JOBS) program for welfare recipients. By October 1, 1990, all States are required to implement JOBS. This innovative program provides enhanced opportunities for AFDC recipients to participate in education, training, and work activities. In addition, Federal funds will be used to reimburse States for child care costs and other work-related expenses, as well as extended child care and Medicaid benefits when an individual leaves the AFDC rolls due to work. The purpose of the Act is to encourage AFDC recipients, especially young single mothers, to develop skills they need to become self-sufficient. For FY 1991, we are requesting one billion dollars in budget authority, the full authorized level, for JOBS program costs, plus $489 million for related child care costs. A key element for effective implementation of this legislation will be a close working relationship and coordinated action with other Departments, such as Labor, Education and Interior. In this context, I am pleased to be able to report to you that at a November national conference on the JOBS program, three Departmental Secretaries (Health and Human Services, Labor and Education) announced a three year technical assistance effort to assist States and Indian Tribes. We will urge that the same coordination efforts take place at the State and local levels in order to prevent duplication and to maximize the use of all available resources.

Increasing child support collections is another effective way to help families become or remain self-sufficient. The Family Support Act strengthens the Child Support Enforcement program by requiring States to establish guidelines in setting the level of child support awards and by providing for periodic review of the appropriateness of such awards.

FSA's programs for low-income home energy assistance, aid for newly legalized aliens, refugee assistance, and community services all fall within the nondefense spending category. Accordingly, proposed funding levels for these programs in FY 1991 are in consonance with the overall domestic spending priorities which have been established over the past several years.

Specifically:

- The budget includes $1.05 billion for the Low Income Home Energy Assistance program (LIHEAP). This program provides supplemental funding to the States for meeting the critical home energy needs of low-income households - in conjunction with other Federal programs.

- For Refugee and Entrant Assistance, the budget request is $369 million, the same level as the 1990 appropriation. This request is based on, and is consistent with, the State Department's estimate that 110,000 federally-funded refugees will be admitted into the United States during FY 1991. Funding for FY 1991 maintains the FY 1990 level of State subsidies for AFDC and Medicaid costs incurred in providing assistance to eligible refugee families, as well as level funding for non-categorical refugee cash and medical assistance, employment services, targeted assistance and voluntary agency matching grants.
  We estimate that reimbursements for the States' share of categorical assistance costs (AFDC and SSI, will be limited to 4 months and we will continue the current 12 months of eligibility for non-categorical refugees. While the number of

months of state reimbursement for categorical refugees is significantly reduced from past year levels, this has no effect on an individual's basic eligibility for categorical program benefits. Reimbursement of state costs for cash and medical benefits provided to categorically eligible refugees will be put more on a par with States' regular AFDC and Medicaid program obligations.

- For State Legalization Impact Assistance Grants (SLIAG) in FY 1991 -- the fourth year of this interim program - $303 million is requested, the same level as appropriated for FY 1990. We are also requesting that funding for FY 1992 -- appropriated last year -- be eliminated. While the Immigration Reform and Control Act of 1986 (IRCA) appropriated $4 billion over four years, the level of spending has not been as high as was estimated when IRCA was passed. Accordingly, we are proposing that SLIAG be maintained as a four-year temporary program.

- The Community Services Block Grant (CSBG) provides Federal assistance to community action agencies for delivering services to low-income individuals and families. We believe that States should assume a greater share of the financial responsibility for provision of services funded under this grant program. Thus, the budget proposes to phase down direct funding for CAA administrative and other costs and require that such activities be funded through appropriations included for the various related Federal programs. For activities to assist the Homeless, the 1991 budget includes $42 million, $20 million more than in 1990. I would also like to mention that a special demonstration program - authorized by Congress in 1990 and designed to examine alternatives to so-called welfare hotels - is proposed for continuation in 1991. However, we intend to transfer this demonstration project to the Department of Housing and Urban Development, a more appropriate location for this housing-related activity.

o In addition, I would like to bring to your attention a new grant program which will provide broad-ranging support for the Commonwealth of Puerto Rico. The grant, formerly administered as a nutrition assistance program through the Department of Agriculture, will give the Commonwealth greater flexibility in tailoring the program to the needs of its low-income households. We anticipate continued Federal financing of domestic assistance programs in Puerto Rico following some form of likely Puerto Rican self-determination action in the near future. Financing block grant programs such as this should be consolidated with other tax and financing programs under the jurisdiction of the Senate Finance and House Ways and Means Committees.

o Finally, $79.2 million is requested to administer the Family Support Administration programs in FY 1991. Proposed language authorizing an estimated $1 million in new user fees to be collected from States for accessing child support locator services in AFDC cases would be treated as an offset to the amount appropriated. An additional $1 million in fees for absent parent and/or employer location services provided to non-welfare cases will be collected under current law. This request will support 1,029 full-time equivalent employees (FTE'S).

In closing, let me say that this budget request reflects our sincere commitment to help the poor by encouraging the economic self-sufficiency of needy families, as well as our determination to pursue and aggressively enforce the support that parents owe their children. We ask your support in achieving those goals. At the same time, we have not ignored our obligation to help reduce the Federal deficit. We believe we have struck a balance between prudently managing the resources required to meet the needs of the poor and identifying opportunities for reducing Federal spending.

BIOGRAPHY OF EUNICE S. THOMAS

Administers federal programs focused on strengthening the family and increasing their self-sufficiency. These programs are Aid to Families with Dependent Children, Child Support Enforcement, Refugee Resettlement, and the Community Services programs. Directs implementation of welfare reform as embodied in the Family Support Act of 1988. Manages a staff of more than 1,900 and a budget in excess of $14 Billion.

Director, Office of Community Services
Family Support Administration

Having worked previously for four cabinet level secretaries in the Departments of Transportation and Labor, Eunice Thomas joined the Department of Health and Human Services in April, 1989 to serve as the Director of the Office of Community Services which administers the following programs: Low-Income Home Energy Assistance, the Community Services Block Grant Program, the Emergency Community Services Homeless Grant Program, the Community Food and Nutrition Program, the Demonstration Partnership Grant Program, and the Discretionary Grant Program.

Other Government Service

- Director of the Office of Small and Disadvantaged Business Utilization, Department of Transportation
- Special Assistant to the U.S. Secretary of Labor

Civic and Community Involvement

- National President of Zeta Phi Beta Sorority, whose membership includes over 70,000 college-educated black women
- Named by Ebony Magazine as one of the "100 Most Influential Black Americans" in 1987, 1988, & 1989
- Active involvement in the National March of Dimes Foundation, National Urban League, NAACP, YWCA, YMCA, and the League of Women Voters

Academic and Personal

- Bachelor of Science--Hampton Institute, Hampton, VA
- Masters of Education--University of Toledo, Ohio
- Ed.D.--University of Oklahoma
- Post Doctoral--Case Western Reserve University, Cleveland, Ohio
- Born in Florida, reared in Georgia and Ohio.

STATEMENT OF MARY SHEILA GALL

Senator HARKIN. Next we will turn to Ms. Gall for your opening statement.

Ms. GALL. Thank you very much. And I do have a statement for the record. And in the interest of time, and so our good friends in the audience do not fall asleep, I will not read it.

Let me just briefly say that our total budget request for Human Development Services is $8.6 billion. That includes a full authorization request of $2.8 billion for Social Service Block Grant Program and some special priorities that I will just briefly discuss here.

The Secretary mentioned this morning our record increase of $500 million over the 1990 level for the Head Start Program to serve up to an additional 180,000 children. This would bring us to serving a total of over 668,000 children in the Head Start Program.

One of our biggest concerns within the Office of Human Development Services is the growing number of children we have coming into the child welfare system. Much of that can be attributed to substance abuse and in particular what Senator Bumpers referred to this morning as those with Fetal Alcohol Syndrome and other similar situations of family violence and child abuse.

Because of our great concern for that particular issue, and to provide the States with additional resources, we are asking for an increase of $47 million in the title IV-B, Child Welfare Services Program to allow States to focus additional resources on preplacement, prevention, and reunification services for families at risk.

We recognize that there has been a dramatic increase in administrative costs for the IV-E Foster Care Program. In the last 10 years costs have increased by 2,800 percent.

The number of children coming into this system during that same period of time increased about 100 percent. The amount of maintenance payments has increased as well, but it is nowhere near the kind of increase that we have seen in administrative costs.

We are proposing to limit the increase in administrative costs to 10 percent per year per State. This proposal, we believe, is workable because it will exercise control over increases in administrative costs and, at the same time, leave maintenance payments and training for foster parents and social workers as open-ended entitlements.

PREPARED STATEMENT

Again, recognizing the dramatic impact of substance abuse on the number of children coming into care, we are requesting an increase of $6 million for child welfare research and demonstration for infants exposed to drugs.

That highlights some of our priorities, Senator. And I would be happy to answer any questions you may have.

[The statement follows:]

STATEMENT OF MARY SHEILA GALL

I am pleased to have the opportunity to talk to you about the Office of Human Development Services' budget request for Fiscal Year 1991. The request of $8.6 billion includes: $2.8 billion for the Social Services Block Grant; $3.33 billion for Human Development Services; and $2.42 billion for Payments to States for Foster Care and Adoption Assistance.

The full authorization of $2.8 billion is requested for the Social Services Block Grant to continue support for a variety of social services in each State.

Within the Human Development Services request, strengthening the family is a primary concern. Increases have been requested: to increase preventive and reunification services for children and their families, to expand Head Start enrollment, and to address the growing problems of drug dependent and HIV-infected infants.

To address the growing needs of families who are called upon to deal with increasingly difficult problems, such as drug abuse, a legislative proposal will be submitted which will increase the incentive funds available to States for child welfare services and stem the rapid rise of Foster Care administrative costs. The fact that administrative costs are or soon will be higher than maintenance costs in some states is a concern to all of us. This escalation of administrative costs has not been correlated with improvements in the quality or quantity of services to children. Limiting increases in this area to ten percent per State each year, while at the same time increasing support for Child Welfare Services with a focus on preventive and reunification services, will result in assuring that Federal dollars are supporting services directly related to preventing inappropriate placements. Foster Care Maintenance Payments on behalf of children will remain an open-ended entitlement.

The request for Head Start of $1.89 billion, an increase of $500 million over the 1990 level, will serve over 668 thousand children and their families, an increase of up to 180 thousand children over the number served in 1990. Research has shown that Head Start makes a difference to both children and parents: children who have had a Head Start experience are healthier, better adjusted and do better upon entering school than their socio-economic peers; and Head Start parents have higher self-esteem and are better able to assume responsibility as the primary educator of their children.

The request of $13.5 million for Child Welfare Research and Demonstration is an increase of $6 million over the 1990 comparable level. This increase will support one-time demonstration projects designed to find innovative ways to meet the immediate nonmedical needs of infants born of crack-cocaine using mothers and HIV-infected children, and to increase access to comprehensive multidisciplinary services.

The budget also includes an additional $1 million to support the 1991 White House Conference on Aging which will help the President, the Congress, the aging community, and citizens of all ages to develop an aging-related policy agenda for the coming decade.

The 1991 budget proposes to maintain 1990 funding levels for the remaining Human Development Services discretionary programs. Service levels will be maintained and, to the extent possible, increased as a result of management and program operation efficiencies.

For Payments to States for Foster Care and Adoption Assistance, $2.47 billion is requested, after a transfer of $47.4 million to child welfare services. This request is an increase of $1.1 billion over the 1990 enacted level.

- A level of $1.7 billion will support maintenance payments on behalf of an estimated 205 thousand children in foster care, as well as the Federal share of State administrative and training costs.

- The request includes $544 million to fund the full estimate of allowable prior year claims.

- A level of $60 million is requested for Independent Living activities designed to prepare foster care children 16 or older to move successfully into independent living.

- A level of $150.5 million will support subsidies for families adopting children with special needs.

Thank you, Mr. Chairman. My colleagues and I will be happy to answer any questions you and the Committee may have.

CHILD SUPPORT ENFORCEMENT

Senator HARKIN. Thank you very much.

Ms. Thomas, I would like to direct your attention to the chart to my right, the one having to do with Child Support Enforcement Program.

Despite a reduction in the Federal matching rate, from 75 percent to 66 percent, the Federal Government has continued to suffer a deficit and the States have continued to achieve a profit in the child support enforcement system.

If you look at the numbers, in the last 3 years total collections from the child support enforcement program have increased by $2 billion. Collections in the AFDC portion of the program now exceed $1.8 billion compared to the administrative cost of $1.6 billion.

Yet despite this, the Federal Government continues to sustain larger and larger losses. By fiscal year 1991 the Federal loss from child support enforcement activities will exceed $.5 billion, and yet State profits will rise to $.5 billion.

This problem is getting so large that we cannot ignore it any longer. Why is it that as profits rise from the Child Support Enforcement Program, Federal Government losses continue to mount? If you look at fiscal year 1990, the States got a little bit over $300 million and the Federal Government lost about $500 million.

Ms. THOMAS. Yes.

Senator HARKIN. What are you going to do about it?

Ms. THOMAS. We have proposed legislation, and let me give you just a brief summary. No. 1, according to the State guidelines that we have now, States can no longer ignore non-AFDC collections.

We have two caseloads. We have AFDC and non-AFDC caseloads. The non-AFDC caseloads do not pay a fee. So we are proposing legislation that would cap the State's spending funds, to 100 percent of their AFDC collections in 1991 and gradually decrease to 66 percent by 1999. This would provide a cost savings.

CHILD SUPPORT ADMINISTRATIVE COSTS

Senator HARKIN. You are proposing a cap next year?

Ms. THOMAS. A cap on administrative cost.

Senator HARKIN. Of?

Ms. THOMAS. So that Federal reimbursement to States for the cost of operating their child support enforcement program be capped at 100 percent on administrative cost of their AFDC collections in 1991.

Mr. STURMAN. Mr. Chairman, if I might amplify something. As to the Child Support Enforcement Program, the figures you have up ahead compare child support collections for AFDC caseload versus administrative costs that the Federal Government pays for both AFDC cases and non-AFDC cases.

The Federal Government—the cost comparison ratios that are portrayed up here are a comparison of total collections for the AFDC caseload against administrative expenses which the Federal Government reimburses for, which includes both categories.

If I might put this into context. In 1991, we estimate total collections of close to $6.8 billion for both AFDC and non-AFDC cases. Administrative expenses, which are what this chart portrays, administrative expenses that we reimburse to States for at a minimum of 66 percent reimbursement—this is by law, nothing that your committee or we have any control over—total close to $1.8 billion.

So we are looking at collections compared to administrative expenses of roughly three times collections to administrative expenses. If you compare AFDC collections against total administrative expenses where the Federal loss occurs, the combined Federal, State, and local relationship, that is, administrative expenses for the program—that is total administrative expenses versus AFDC collections—we are looking at $2.2 billion in child support collections for the AFDC caseload versus $1.8 billion for administrative expenses.

So that the net profit to the program, no matter which side you are looking at, is $400 million. The issue is that the law, that is, title IV–D of the Social Security Act consciously weighed the incentives toward the States in order to run a good program. Whether the Federal Government has a loss or a profit is not so much the issue. The fact is that at the Federal level and the State level we are receiving more in AFDC collections than you have in total administrative expenses for the program, whether it is for AFDC collections or non-AFDC collections.

It is because of the nature of the matching rate, which is 66 percent Federal for regular cost, 90 percent for systems, 90 percent for paternity establishment, plus out of the Federal share of AFDC collections, we pay the States an incentive payment. So the system weighs the cost in favor of the States.

We have proposed legislation, as Ms. Thomas was saying, which is an attempt through both fees collected for non-AFDC cases and proposed legislation to tie State reimbursements for administrative costs to what they are recouping in terms of collections. So, it benefits the Federal Government a little bit more, so that we get the cost down to a minimum zero balance for the Federal Government.

That is not so important as the fact that at the Federal level and the State level we are collecting more in child support than it is costing the Federal Government and the State government combined. And there are tremendous social values in the fact that we are running an effective child support program, and the program is becoming more effective every year.

And yes, we share your concern tremendously that the Federal Government ought to be a net profit. But even if we are not, it is United States' society that benefits.

Thank you.

CHILD SUPPORT ENFORCEMENT

Senator **Harkin**. Well, you can say there is no inequity, but the fact is, we keep losing and the States keep gaining.

Mr. **Sturman**. We agree completely. And we proposed legislation for several years running, Mr. Chairman. And so far our success in getting legislation to make the Federal Government's side of the equation, the taxpayer at the Federal level, benefit—we have not been successful in getting Congress to enact that legislation yet.

And we are hopeful, we are still hopeful we are going to get that. And we look for your support.

Senator HARKIN. Well, is there something else we can do to get the States to improve the performance of their systems?

Mr. STURMAN. I can try. From our standpoint I think it is the judgment of the child support program that we are running an improving program every single year.

I think if the committee is interested in helping us by including in appropriations language, the kind of proposals we have proposed as changes to title IV-D of the Social Security Act, that we would be happy to work with the committee to include in appropriations language the kinds of proposals that we think are going to benefit the Federal taxpayer, not just the entire program.

And we would be very happy to work with you on that, because we think that the kinds of changes we are proposing are more important—better cost effectiveness. It can be done either by changes in substantive law or through appropriations—proposed legislation. And we would love to be able to work with you on that.

Senator HARKIN. Would it be a proposal, do you think, just to say that if the States improve their quality that they will get Federal financing, or if they do not, they would get less. Something like that?

Mr. STURMAN. Yes, sir. I might note just so that you are aware. If every State ran a program as good as Iowa's, we would be in a positive cost-effectiveness ratio for the Federal Government as a whole. Iowa is running a very, very good program. Other States do not run a program as good as your State.

Senator HARKIN. What is Iowa's cost-effectiveness ratio?

Mr. STURMAN. We can put that in the record if you like. But I know for a fact for Iowa, for example, just by comparison purposes, your State runs, in terms of cost-effectiveness ratio, a rate of around $2.50 in return in AFDC benefits for every dollar of administrative expense that is incurred. Iowa is like the second or third or fourth for the Nation as a whole.

Other States—our problem is that other States are running negative balances, and that is why you have got the red line down below the chart that exceeds the blue line up above.

Senator HARKIN. Iowa is running third at a rate of $2.41.

Mr. STURMAN. That is correct.

Ms. THOMAS. That is correct.

Senator HARKIN. But it looks like about one-half the States are below the $1 level.

Mr. STURMAN. Yes, sir; that is correct. And that is because of the nature of the way the Federal law is written in terms of how you distribute the Federal share of AFDC collections. And that in and of itself is not bad from the standpoint of the tax system for the country as a whole. It reflects poorly on the Federal level only because that is the way the law is written.

But if you look at it in an entire perspective the whole country benefits by the program.

FAMILY SUPPORT ADMINISTRATION VACANCIES

Senator **Harkin**. The Bush administration is in its second year yet there is still a vacancy to head the Family Support Administration. Are you going to be the new Administrator?

Ms. **Thomas**. I really cannot answer that. Dr. Sullivan would have to answer that.

Mr. **Sturman**. Mr. Chairman, just to do a little stroking, whether it is or is not, she is doing a great job. She really is.

FOSTER CARE

Senator **Harkin**. Let us talk a little bit about foster care. As you can see on the charts the administrative costs have gone up by 2,800 percent in the last 10 years. In 1982 the level for administration and training was 19 percent and now it has gone up to 51 percent.

We spend more on administration and training than we do on the whole program. This activity has increased 2,800 percent compared to a 99-percent increase in the number of children who have been served and a 233-percent increase in maintenance payments.

Is there any evidence that we are getting improved or increased service as a result of these tremendous increases in administrative costs?

Ms. **Gall**. Before I answer that, let me also note that if we continue now without addressing the issue of administrative costs, you will find that within the next couple of years administrative costs will exceed maintenance payments.

Administrative costs for this particular program also include service-related activities such as case reviews, as well as overhead and other more typical administrative related issues. In our view we have not seen a measurable increase in quality or numbers of services to those children as the administrative costs skyrocket.

We want to put some measure of control on administrative costs, and at the same time recognize the need for additional moneys to go directly to services to prevent families from breaking up in the first place, or when it is necessary to remove a child from the home, to make every effort for reunification. And if that is not possible, to move a child into a plan for adoption, so that that child has a permanent loving home. That is why we feel that this proposal is very balanced. It does recognize the need to provide additional funding for direct services to those children and their families.

I might also add though, Senator, I do not consider this the answer to the many problems that are facing our foster care system today. This is an important first step, but only a first step. Because of the new challenges that we are facing due to substances abuse and the higher numbers of children coming into care, there are many other issues that need to be addressed in terms of coordination of services, and new ways to do business.

This is why I say it is an important first step, but it is only a first step.

Senator **Harkin**. Is there any evidence that States are shifting costs to this open-ended entitlement program, thus freeing up moneys for other projects?

Ms. **Gall**. Yes, sir; we do have some evidence that that is taking place.

Senator **Harkin**. I also want to work with you on your proposal to cap the cost. I proposed that last year, but we were not successful. Maybe we will be successful this year.

Another area of interest: In fiscal year 1990, we approved a $3.5 million appropriation for improved outreach for SSI. Is this program being coordinated with the State and area agencies funded under the Older Americans Act?

Ms. **Gall**. Yes, sir.

Senator **Harkin**. It is?

Ms. **Gall**. It is.

Senator **Harkin**. Is there any request for money? Did you request any money for this year?

Ms. **Gall**. No; no additional funds are requested.

Senator **Harkin**. Did you even request the $3.5 million?

Ms. **Gall**. No.

Senator **Harkin**. OK, thank you all very much. I appreciate the testimony. And we will work with you on these items.

Ms. **Gall**. We appreciate your support on that Senator. Thank you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. Thank you. I have other questions that I will submit to you in writing.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

FAMILY SUPPORT ADMINISTRATION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

VACANCY AT THE TOP OF THE FAMILY SUPPORT ADMINISTRATION

We're in the second year of the Bush Administration and there is still a vacancy to head the Family Support Administration.

Question. Why is it taking so long to fill this key position which is responsible for billions of dollars in welfare and anti-poverty programs?

Answer. Several candidates have been considered for this position and we remain concerned that this position is still vacant. Nevertheless, because of the good work of our employees in this area - including those who are serving in an acting capacity -the work of the agency is being done.

Question. Does this reflect a low administration priorityon Federal assistance to families?

Answer. No. Supporting children and families remains a priority of both the President and this Department. Although the position is vacant, we have an Acting Assistant Secretary and the Family Support Administration is working well. As an example, the regulations that were required to implement the Family Support Act of 1988 were issued in record time.

Question. When will this vacancy be filled?

Answer. Secretary Sullivan has indicated that he intends to fill this position as soon as possible.

FEDERAL LOSS FROM CHILD SUPPORT PROGRAM

In the last three years total collections from the Child Support Enforcement program have increased by $2 billion. Collections in the AFDC portion of the program now exceed $1.8 billion, compared to administrative costs of $1.6 billion. Yet despite this growing success, as you can see from the chart, the Federal government continues to sustain larger and larger losses. By fiscal 1991, the Federal loss from child support enforcement activities will exceed half a billion dollars, yet State profits will rise to half a billion dollars. I know the Administration has offered proposals in the past to correct this imbalance, which Congress has largely ignored, but the problem is now getting so large, it may get a lot more attention.

Question. Why is it that, as profits rise from the child support enforcement program, the Federal government's losses continue to mount?

Answer. Overall, the Federal government gives back to the States an average of 86 percent of total program costs, not including the State's share of AFDC collections. The financing of the Child Support Enforcement program, as established in Title IV-D of the Social Security Act, necessarily returns a greater share of program revenues to the States than to the Federal Government. States in FY 1991 will keep approximately half of the AFDC collections and, in addition, receive about 33 percent of the Federal share of AFDC collections as incentives. Further, the Federal Government will pay 66 percent of the costs of administering the program and 90 percent of the cost of approved computer related systems and paternity establishment programs. In FY 1991, States will return to their treasuries $2.88 for every $1.00 they spend on child support enforcement. In stark contrast, OCSE will return to the Federal treasury $1.00 for every $1.77 it spends.

In order to reduce Federal losses, we are proposing a new method to promote increased program efficiency and effectiveness. This proposal would mandate that State Child Support Agencies collect a dollar on behalf of AFDC families for every dollar of matching funds the Federal government pays for child support activities on behalf of both AFDC and Non-AFDC families.

Federal matching funds for administrative costs would be capped at the total amount of collections on behalf of AFDC families for States that do not achieve this balance between AFDC collections and total administrative costs. After FY 1991, the cap on Federal administrative matching funds for the States that continue not to meet this criteria would be progressively reduced each year until FY 1999.

The vast majority of States that collect more money on behalf of AFDC families than the Federal government pays them in matching administrative funds would continue to receive 66 percent Federal Financial Participation (FFP) for regular administrative costs. This proposal will motivate poorly performing States to improve their services in the collection of AFDC support payments and thereby improve the Federal financial position in the program.

Question. According to data from the Congressional Research Service, collections from absent parents could eventually rise to $30 billion annually, six times what they are now. Does this projection mean the Federal loss from the child support enforcement program could conceivably get six times as big as it is now, perhaps $3 billion a year?

Answer. We project that Federal losses will increase to $800 million by 1995. There is no direct relationship between collections and Federal losses. Large increases in collections resulting from the use of mandatory guidelines in AFDC cases will result in positive Federal gains. While guidelines will affect both AFDC and Non-AFDC cases, the Federal and State governments only share in the AFDC collections.

The CRS report is referring to findings from research sponsored by the Office of Child Support Enforcement in which "Estimates of National Child Support Collections Potential" were made. This research found that absent parents could have paid about $26.6 billion in child support in 1984 if awards had been established using "guidelines" and considering the non-custodial parent's financial capability to pay support. However, since the bulk of this larger national collections potential would likely come from middle and upper-income absent parents - rather than on behalf of AFDC or other poor families, the increase in total program costs associated with the higher level of total collections could conceivably exceed the additional Federal revenues resulting solely from the increase in AFDC collections. Under these circumstances the Federal loss could grow, though not necessarily proportionately.

While merely collecting more money does not necessarily assure the Federal government added revenue, it is a step in the right direction. If existing AFDC orders can be increased under proposed guidelines and under the review and modification requirements of the Family Support Act and if administrative costs to enforce these orders remain relatively stable, program efficiency will increase and Federal losses will decrease.

This entire scenario, however, is contingent on States quickly adopting and vigorously using the support enforcement tools authorized by the Family Support Act of 1988.

Question. I understand that you have three legislative proposals that collectively would reduce Federal expenses by $32 million in FY 1991. Could you discuss each of these three proposals and tell us how much each would save?

Answer. State child support programs have improved but not nearly enough, or in a way, that would reduce the deficit to the Federal government. We are, therefore, proposing new methods to promote increased program efficiency and effectiveness, as follows:

Cost Recovery: This proposal would require states to recover the cost of both AFDC and Non-AFDC child support enforcement and paternity establishment services, based on ability to pay. Recovery of costs would not be applied to individuals with incomes below 150 percent of the poverty line, and a sliding recovery scale would be used for individuals with incomes above 150 percent. These costs could be recovered from either the custodial parent, the non-custodial parent, or both, depending upon each parent's ability to pay. AFDC recipients and other mandatory IV-D clients would not be required to cover their support enforcement costs. And only child support collections that exceed the current support obligation, could be used to recover costs.

This proposal would also require States to modify the present Non-AFDC application fee by basing it on a sliding scale according to income level and waiving it for low-income families. Overall this proposal is projected to save $30 million in FY 1991; States would save an estimated $15 million in FY 1991.

Increase Program Efficiency: This proposal would stimulate the States to perform better in relation to both their AFDC and Non-AFDC caseloads, by limiting the amount of Federal funds available for reimbursement for administrative expenditures for States that do not operate efficiently. Specifically, it would limit reimbursement for States that are not effective in pursuing their AFDC collections. The current financial structure, including incentive payments, has been deficient in altering the behavior of poorly performing States. Capping the Federal match for administrative costs will stimulate these states to increase collections and to become more efficient.

Beginning in FY 1991 for States that are not effective (do not collect a dollar on behalf of AFDC families for each Federal dollar spent on administrative costs), the amount of Federal funding for State administrative costs would be capped at an amount equal to the State's total child support collections on behalf of AFDC families. The Federal funding limit for States that continue not to meet the effectiveness criterion would be phased down from 100 percent of AFDC collections in FY 1991 to 66 percent in FY 1999. This proposal is projected to result in a savings of $10 million in FY 1991.

CSE Services for recipients of other Federal Assistance Programs: This proposal would provide general legislative authority under which recipients of other Federal benefit programs could be required to cooperate in the establishment of paternity and child support enforcement as a condition for their continued receipt of Federal assistance. The proposal would move recipients of other types of Federal assistance toward self-sufficiency by providing additional resources and reducing the amount of public assistance these families require.

This change would result in additional child support State/local administrative costs; estimated savings to affected programs will be displayed as direct offsets to their costs. For example, in FY 1991, savings of $50 million as a result of this proposal are included in the USDA's Food Stamp request.

The proposal would make child support available to an expanded number of families not now receiving it. For example, the Food Stamp program is envisioned as one of the first programs affected. Under the Food Stamp-Child Support linkage, we estimate that 210,000 additional families would receive child support payments as a direct result of this proposal. As a result of these child support payments, both the family and the Federal government would benefit. The total amount of income and resources available to the family would be increased and the amount of Food Stamp benefits paid by the Federal government would be decreased.

Question. Is it unreasonable to expect the Federal government to break even in the Child Support Enforcement Program, particularly if collections continue rising at the current pace?

Answer. The Child Support Enforcement program continues to collect more and more child support; but in FY 1989, for the first time since the program's inception in 1975, the program had a net cost to the taxpayer. Some State Child Support Programs are performing poorly; and some parents are being allowed to shirk their financial responsibility at the expense of the taxpayers.

Over the past five years, the Federal share of AFDC collections has remained fairly consistent, around 30 percent after incentive payments. During the same period, AFDC collections have increased 7 to 13 percent per year; and the Federal share of expenditures has increased 7 to 18 percent per year. Without changes to the program's present financial structure, the Federal loss can be expected to continue to increase. Experience indicates that program savings do not necessarily increase when collections do. Only more effective and efficient State performance can produce a radical break from this pattern in future years, absent a major modification of the statutory funding structure.

INEFFICIENT STATE CHILD SUPPORT SYSTEMS

Most States continue to be highly inefficient, yet they still make a profit at the expense of the Federal government. Under the current system the Federal government will reimburse the States for any State expenditure made toward child support enforcement. In a recent study reported by the Congressional Research Service, 18 States received grades of "D" or "F" for the poor quality of their child support systems.

Only a few States actually return a profit to both the State and Federal governments from Child Enforcement programs. If more States don't improve their efficiency, Federal losses will undoubtedly continue.

Question. Doesn't the current overly generous financing system actually make your job more difficult in trying to convince States to improve the performance of Child Support systems?

Answer. Unquestionably, the financing of the Child Support Enforcement Program, as established in Title IV-D of the Social Security Act, is generous from a State and local perspective. Indeed, the law was deliberately structured that way to motivate States to establish and operate effective support enforcement programs. Some States have responded in this fashion. Others seem content to provide program services in a manner well below their potential capability, perhaps in part because even mediocre performance brings a financial return to the State and/or locality under the current financing structure. Changing this latter situation is the intent of our legislative proposals.

Question. If the quality of programs were improved, wouldn't everyone involved gain?

Answer. We believe so. The child support enforcement program is vital to the well-being of American children--more than 15 million of whom are now living in single-family households, mostly headed by women. Recent statistics show that more than 40 percent of families headed by single women live in poverty.

Congress and the Administration have addressed the needs of these families through the passage of the 1988 Family Support Act. This legislation takes a significant step in helping welfare families attain self-sufficiency. Provisions in this legislation include the mandatory use of guidelines in setting support orders, the tightening of paternity establishment requirements, the use of immediate wage withholding at the time a support order is established, and automation in all States by October 1, 1995. Full implementation of this legislation will most certainly help the women and children of America.

If program effectiveness and efficiency were improved, everyone would gain, including the taxpayer and children in financial need.

Question. Should the Federal match be reduced? What would it save the government if the match were reduced from 66 percent to 50 percent?

Answer. Using FY 1989 as an illustrative year, the Federal deficit would decline from $444 million to $230 million if the Federal match rate were reduced from 66 percent to 50 percent - a saving of $214 million, assuming no reduction in total program level.

We would prefer the Administration's proposed financing to a reduction in matching. Any consideration of reducing the rate of federal financial participation must also take into account the resultant responses of State and local government. We would be concerned that by cutting the Federal match, some States might end up with no savings from program activities. It is difficult to predict how States would respond, but we believe that States would respond differently to a redirection in savings than to an elimination of all savings or net increased cost to the State. States could react to a cut in federal funding by maintaining the planned level of child support enforcement services, necessitating an increase in State and/or local funding to offset the lesser amount of money coming from the Federal government. Conversely, States and localities could simply reduce program services, contracting the size of their support enforcement effort so as to invest no more State and/or local money than envisioned at the current federal matching rate. This, however, would place them in jeopardy of not meeting program audit requirements which could result in loss of funds through the imposition of audit penalties.

DUMPING CHILD SUPPORT COSTS ON FEDERAL GOVERNMENT

Several States have learned how to shift court costs relating to child support caseloads into the program and have the Federal government pay for State court costs. Under these agreements, an application for routine family court services is designated as an application for child support enforcement services.

Question. Besides enabling States to have their administrative costs partially reimbursed by the Federal government, are there other reasons why States might incorporate most of their child support caseload into the Child Support Enforcement Program?

Answer. One reason a State might want to incorporate all child support cases into the IV-D system, besides getting administrative costs reimbursed by the Federal government, is so that there will be a system in place to monitor each and every case. If it is felt that all child support cases are potentially problematic and might require the location or enforcement attention of the IV-D system, then it makes some sense to include all cases automatically. In that manner, time and effort can be saved in establishing the right of the IV-D system to take action on a case when and if it becomes necessary to do so.

Another reason States may include all cases in the IV-D system is to get incentive payments for the collections that come in regularly from these cases. Certainly there are non-IV-D cases that already pay regularly and involve no enforcement services other than passing the money to the family. These collections could then be included in the States' totals and be eligible for incentive payments. It should be noted that there is a "cap" on the amount of money a State can receive in Non-AFDC incentive payments. The "cap" is currently set at 115 percent of any AFDC incentive payment.

Finally, some maintain that, by including all child support cases in the IV-D system, they have better control over the outcome. This results in equal treatment of all cases with similar types of child support awards and enforcement tools being used.

Question. Why haven't most, if not all, states done this?

Answer. Some States are far more prone than others to favor child support payments directly between the effected parties in divorce cases. Even in jurisdictions where support is paid to a governmental entity such as a clerk of the court, the official in question is frequently independently elected and may not wish to enter into a contractual arrangement with the IV-D agency, an arrangement that provides funding but at the "cost" of performance expectations, controls of one form or another, and exposure to federal and/or state audits. Given the purely financial incentives for change in Title IV-D, the fact that more States have not moved to bring all child support cases into the IV-D system is testimony to the strength of States and local traditions and practices, and the non-monetary considerations that impact the decision-making process.

Question. If more States follow this path, what will be the impact on the Child Support Enforcement Program and the Federal deficit?

Answer. If more States follow this path, it is likely that administrative costs for the Federal government will go up with no appreciable increase in AFDC collections. All AFDC collections are already in the IV-D system. Non-AFDC collections will rise as States take credit for collections that are currently being made without IV-D services. Non-AFDC incentive payments, which are entirely funded by the Federal government, will also rise in some States. It should be noted that Non-AFDC incentives are "capped" at 115 percent of AFDC incentives, thus limiting their growth potential.

There are several States that have historically included all child support cases in the IV-D system. In recent years, additional states have started to "blanket-in" all child support cases into the IV-D program, thereby refinancing ongoing State or local administrative costs at Federal expense and potentially qualifying for larger Non-AFDC incentive payments.

If more States follow the path of converting all child support cases into IV-D cases, there could be a substantial impact on the net savings of this program. The impact is actually dependent on the approach States take. There are many States that spend more money on total administrative costs than they collect on behalf of AFDC families. The Federal government pays 66 percent of

States' administrative costs for running the Title IV-D Child Support Program. States receive this Federal money regardless of their efficiency. Sixty-six percent is available for all allowable IV-D costs for both AFDC and Non-AFDC portions of the program, even though State and Federal governments only share in the AFDC collections. The collections made on behalf of AFDC families are used to offset Federal and State expenditures for Title IV-A (AFDC). It is, hence, highly desirable from a Federal Budget standpoint to collect more money on behalf of AFDC families than is spent on the child support program.

If States that choose to include all child support cases in their IV-D program collect enough money on behalf of families on AFDC to cover total administrative costs and incentives paid by the Federal government; then there is no federal deficit or net loss to the taxpayer. States need to collect roughly $3 on behalf of AFDC families for each dollar spent in operating the entire program (AFDC and non-AFDC combined) in order for the Federal government itself to break even. However, if such States do not maintain or improve their efforts on behalf of AFDC families, the child support program will continue to create a large Federal deficit and a net loss to the taxpayer.

CHILD SUPPORT TECHNICAL ASSISTANCE

Question. Would you agree that the least efficient States could learn a lot from the most efficient States in the Child Support Enforcement Program?

Answer. Certainly States can benefit from the expertise of more efficient, similarly situated States. However, such an exchange would only be fruitful if the least efficient States were willing to invest the level of resources and commitment in their programs as many of the more efficient States. Often performance differences simply reflect the resources and commitment a State is willing to invest in its program and not nationally innovative management techniques or program practices.

OCSE has disseminated a vast amount of technical material geared to helping States improve their programs. There has also been extensive technical assistance provided to State and local agencies, directly and by OCSE contractors.

Question. Why not provide a small amount of technical assistance funds for the highest performing States to help the other States improve the efficiency of their Child Support Enforcement operations?

Answer. We do not believe that providing technical assistance funds to high performing States to assist other states will result in a positive gain to the program. Congress has provided States with the necessary tools for effective and efficient administration. States must be willing to make the commitment, provide the management, and invest the resources necessary to insure that the benefits of these tools are fully realized.

In addition, there are many information-sharing resources currently available to States to take advantage of tried and true techniques. Technical assistance is currently available from both OCSE headquarters and from regional office staff, as well as through training and technical assistance contractors funded by OCSE.

IMPROVING STATE PERFORMANCE IN CHILD SUPPORT ENFORCEMENT

Under the current financing of the Child Support Enforcement program, States can run inefficient programs and still make a profit.

Question. What would happen if States received incentive payments only if they performed above the national average of child support collections per dollar of total administrative costs?

Answer. The net cost to the Federal government of the Child Support Enforcement Program in FY 1989 is approximately $470 million; incentive payments from the Federal government to the States totaled approximately $238 million. In that year, twenty-four States had cost effectiveness ratios which fell below the national average for both AFDC and Non-AFDC collections.

Incentive payments made to the twenty-four states with cost effectiveness ratios below the national average in both categories totaled $78 million. If incentive payments had not been made to these twenty-four States, the net cost to the Federal government for the program would have fallen from $470 million to $392 million.

Question. How much would this approach save the Federal government in FY 1991?

Answer. With regard to FY 1991, there are no estimates at present of the number of States which will have cost effectiveness ratios below the national averages. However, if it is assumed that the proportion of the total amount of incentives payments made remains the same, an estimate can be made based on the FY 1989 percentages. In FY 1989, 29% of the incentive payments went to States with both cost effectiveness ratios below the national averages. Total incentive payments for FY 1991 are estimated to be $332 million and the cost to the Federal government of the program is estimated to be $521 million. Based on the FY 1989 percentages, the cost to the government could be reduced to $425 million if no incentive payments are made to States with both ratios below the national average. This is assuming that all States replace the "lost" federal funds from other sources and thereby achieve their currently projected levels of collections and other program outputs.

LACK OF INCENTIVE TO IMPROVE CHILD SUPPORT EFFICIENCY

Despite the reduction in the Federal matching rate (from 75 percent to 66 percent), the Federal government has continued to suffer a deficit and the States have continued to achieve a profit in the child support enforcement system.

Question. Are States likely to minimize costs when most of the costs are paid for by the Federal government?

Answer. The current structure of the Child Support program, which is based on reimbursement of costs, may not provide adequate incentives to States to minimize costs. However, as has been noted, there is a legislative proposal which, by limiting reimbursement, may act to provide greater incentives to States to increase the efficiency of their programs. At present, States receive the same matching funds regardless of the efficiency of their programs. A proposal to limit matching funds for less efficient States to the amount of AFDC collections will result in States' making greater efforts to minimize costs and to maintain higher rates of collection for AFDC cases.

Question. Are States running inefficient programs in part because States require local levels of government to contribute to the running of the program?

Answer. There are no data available to either validate or refute such a hypothesis. In this context, however, it should be noted that States are required to pass through incentive payments to those political subdivisions of the State that participate in costs of the program, taking into account the efficiency and effectiveness of the political subdivision. Certainly there are better performing local political subdivisions in many States which contribute to the non-federal share of the program's administrative costs, but still show a direct profit because of sizable incentive payments earned by their high collections and cost effectiveness.

USER FEES AND COST RECOVERY IN CHILD SUPPORT PROGRAM

Federal law requires States to charge an application fee of up to $25 for CSE services for non-AFDC families. Some States charge the full $25, some less, and others use State funds to pay the fee or seek collection from the noncustodial parent. In addition, State Child Support agencies are allowed to recover the actual costs of their services to non-AFDC families from either the custodial parent or the noncustodial parent, once current support has been covered?

Question. Is it true that many States choose to pay the application fee out of State funds and choose not to recover their costs because such fees and recovery costs decrease the amount of the State's expenditures eligible for Federal funding?

Answer. Child Support Enforcement services for individuals not receiving AFDC are available upon application. The IV-D agency state plan must provide that an application fee will be charged for each Non-AFDC individual who applies for services. The State may collect the application fee from the individual applying for IV-D services or pay the application fee out of State funds. The fee may not exceed $25 and must be uniformly applied on a statewide basis. States that pay the fee on behalf of the applicant frequently set a fee schedule at a very low rate. Several States have in fact set this fee as low as one cent per application.

States also may elect in their State plans to recover costs incurred in excess of fees collected to cover administrative costs under the IV-D state plan. A State that elects to recover costs may collect, on a case by case basis, either actual or standardized costs from: (1) the individual who owes a support obligation to a Non-AFDC family on whose behalf the IV-D agency is providing services; or (2) the individual who has filed an application for IV-D services. ONly a few state recover full costs.

In FY 1989, about $7 million was collected from fees and cost recovery. These monies are deducted from total administrative expenditures before the expenditures are divided into State and Federal shares. They do not work to the States detriment; indeed, reducing a State's net expenditures can serve to increase federal incentive payments.

Question. How would your propcsal requiring States to charge Non-AFDC individuals for child support services and service costs from such individuals make State programs more efficient?

Answer. The Administration's proposals will reduce States' motivation to "blanket-in" all child support cases into the IV-D program, thereby refinancing ongoing State or local administrative costs at Federal expense and potentially qualifying for larger federally-financed incentive payments for non-AFDC collections.

Question. Would such a provision change the division of costs and benefits in the program?

Answer. The division of costs and benefits in the program would not change. States would still pay 34 percent of all regular administrative costs and the Federal government would pay 66 percent of such costs. If States should choose, some of the savings could be used to finance better services, such as paternity establishment, for low income families. However, total costs borne by government at all levels would be reduced by the amount of money collected for fees and cost recovery, and overall savings to the taxpayer would increase.

Question. Do you have data to support your conclusion?

Answer. The President's Budget anticipates a five-year cumulative savings of $200 million from the child support cost recovery legislative proposal. Savings to the federal government for FY 1991 are estimated to be $30 million.

WINTER FUEL ASSISTANCE EMERGENCY

The combination of high fuel prices and cold weather has left millions of low income persons with energy bills quadruple their normal level this winter. Consequently, many States appear in danger of exhausting their Low Income Home Energy Assistance funds, unless they substantially reduce payments per household in an attempt to at least provide some assistance to those with the greatest needs. Several Senators have already written to the Appropriations Committee, recommending an urgent $300 million supplemental.

Question. What are you advising States to do in response to this winter's energy crisis? Do you have any evidence that applications for energy assistance are in fact higher this year?

Answer. The LIHEAP block grant gives States the flexibility to target assistance to the households that have the greatest need. States may increase the portion of their LIHEAP allotments that they allocate for heating assistance, reduce the portion they allocate for administration, and reduce or eliminate the portion they transfer to other block grants or carry forward to the next program year. They also have the option to designate petroleum overcharge and State funds for use under the LIHEAP program.

The FY 1990 Winter Telephone Survey conducted by the Office of Energy Assistance asks the States for information about applications for LIHEAP heating and crisis assistance (approved and denied) for the 3-month period from October 1 to December 31, 1989. The surveys have just been completed, and the information is currently being compiled and analyzed.

Based on data submitted by the States, we have some preliminary information with respect to applications. Nationwide, there appears to have been a decrease in the number of heating assistance and crisis assistance applications received in the first three months of FY 1990, compared to the same period last year.

For the heating assistance program, 22 States have reported increases in the number of applications they have received in the first three months of FY 1990, compared to the same period in FY 1989. 26 States have reported decreases in the number of applications. (Data is incomplete for 3 States.) For the crisis assistance program, 20 States have reported increases in applications, while 15 States have reported decreases.

Question. How many States have requested permission to utilize their entire year's funding to meet the winter crisis, leaving nothing in reserve for weatherization programs and summer cooling assistance?

Answer. To date, no State has notified us of their intent to utilize their entire year's funding to meet the winter crisis, leaving nothing in reserve for weatherization or summer cooling assistance. Minnesota scaled back their conservation program efforts in order to assist households with the high costs of oil and propane. The District of Columbia may consider shifting cooling assistance funds into crisis if they exhaust their crisis assistance funds. North Dakota and South Dakota are not using LIHEAP funds for weatherization this year. They are reprogramming the funds into their regular heating assistance program.

As of February 13, we had received requests from five states (Vermont, Maine, New Hampshire, Massachusetts, and Iowa) to receive third quarter funds during the first half of the fiscal year.

Question. I understand you have recently completed a telephone survey. I would like to have a report on this survey by February 15, to get an up-to-date assessment of this winter's Low Income Home Energy Assistance Program. The report should include State-by-State expenditures to date and anticipated shortfalls, as well as applications comparing this winter to last, and other significant data covered in previous surveys. Can you get me such a report?

Answer. During the week of January, 15, 1990, the majority of states participated in our FY 1990 winter LIHEAP telephone survey. Once the surveys are completed, we need to edit the data and call back states for either incomplete or inconsistent responses before we can prepare accurate state-specific tables. Based on our experience with our previous telephone surveys, the final results of our FY 1990 winter telephone survey should be available by the end of March. We should be able to share our draft preliminary results by the middle of March, if not sooner.

STATE RESPONSE TO THIS WINTER'S ENERGY NEEDS

Question. How have States responded to pressures on their LIHEAP operations because of the recent cold weather and energy price increases?

Answer. The LIHEAP block grant gives States the flexibility to target assistance to the households which have the greatest need. To respond to the volatile cold weather and temporary energy price increases, States can adjust their LIHEAP eligibility standards and benefit levels, the amounts transferred or carried over, and types of assistance provided, to best meet the needs of their citizens. Fortunately, the exceptional warm weather in January and February has relieved the pressure on many states.

- Delaware reprogrammed $10,000 of administrative funds into the crisis program because crisis funds were rapidly depleting due to the cold weather.
- Massachusetts is considering using their crisis assistance reserve funds to continue its heating program, if necessary.
- Ohio and Indiana have designated petroleum overcharge funds for use under their FY 1990 LIHEAP programs to respond to the recent cold weather and energy price increases.
- North Dakota and South Dakota are not using LIHEAP funds for weatherization. They have reprogrammed the funds into regular heating assistance.
- Five States (Massachusetts, Maine, Vermont, New Hampshire and Iowa) have requested third quarter funds in the first half of the fiscal year. All of these States have received these funds.
- Minnesota scaled back their conservation program efforts in order to assist households with regular heating and crisis assistance.
- Indiana targeted funds toward lower income households.

Question. Has there been any significant movement to commit oil price overcharge settlement money to LIHEAP as a supplement to Federal appropriations?

Answer. We have not seen an overall increase in the percentage of oil overcharge funds being designated by the States for their LIHEAP programs. We assume this is an indication of State spending priorities.

Question. Have States reduced the money they expected to transfer to other block grant programs or carry over into 1991?

Answer. Information about the States' block grant transfers for FY 1990 has been collected as part of our FY 1990 winter LIHEAP telephone survey. There is no change in the number of States (29) reporting that they transferred funds. However, we cannot be confident of the amounts transferred until we have finished reviewing the data and have discussed discrepancies with the States. Preliminary results from the survey will be available by the middle of March.

Question. Have reserves set aside for emergency aid been affected?

Answer. Although weather is averaging out to normal, the cold December and temporary price increases in fuels used by a quarter of LIHEAP-eligible households caused State programs to spend funds earlier in the fiscal year than normal. As a result, states would be less able to respond to a late winter cold snap. The weather service predicts normal to warm weather for most of the country.

Question. To what extent have States reduced benefits or curtailed eligibility?

Answer. Since LIHEAP is a block grant, a LIHEAP grantee may adjust LIHEAP eligibility standards and benefit levels, the amounts transferred or carried over, and types of assistance provided to best meet the needs of citizens.

- No States have as yet begun transferring funds from other block grants to LIHEAP. A review of preliminary data, however, indicates that the same number (29) may divert funds from LIHEAP as in FY 1989.
- Some States have lowered their average benefit levels. Indiana's average heating assistance benefit decreased $22 to $236 in FY 1990. Maine's average benefit level is $245, down $65 from last year. Michigan and Illinois have lowered their average crisis assistance benefits.
- Indiana targeted benefits on those below 125% of poverty for all households.
- In FY 1990 Wisconsin started paying benefits only to those in need. Wisconsin use to give automatic payments to SSI recipients whether or not they lived in public housing or had any utility bills.
- Before the onset of cold weather, West Virginia cut all LIHEAP benefits by 20% in anticipation of reduced LIHEAP funding.
- Before the onset of cold weather, Maryland eliminated its LIHEAP weatherization component in FY 1990 in anticipation of reduced LIHEAP funding.

STATE LEGALIZATION IMPACT ASSISTANCE GRANTS

Last year, Congress reduced FY 1990 appropriation for State Legalization Impact Assistance Grants (SLIAG) by $555 million, but restored these funds for use in FY 1992. At that time, there was an unspent balance of $1.6 billion in previous appropriations, with only $200 million having been spent by the States. I understand that the latest data shows an unspent balance of $1.8 billion, with expenditures of only $300 million.

Question. Why have States been making such slow progress in utilizing these funds?

Answer. Currently, States have drawn down less than $500 million of the over $2.1 billion already appropriated for SLIAG -- less than 25 percent.

In order to interpret these figures, it is important to realize that SLIAG has two components: (1) a funding source that reimburses State and local governments for costs they incur if newly legalized aliens participate in existing, generally available public assistance and public health programs; and (2) a funding source that provides new adult education programs for access to newly legalized aliens.

One reason for the relatively low drawdown of SLIAG funds is that newly legalized aliens are accessing services in public assistance and public health assistance programs at rates far less than either States or the Federal government had estimated when the Immigration Reform and Control Act of 1986 (IRCA) was enacted. As a result, last summer HHS revised downward its estimate of the "Federal offset" -- basically the Federal share of Medicaid costs associated with newly legalized aliens. This increased the amount of funds available to States by $528 million. The statutory requirement that we reduce the Federal offset because costs were lower than expected actually increased the amount of funds available to States even though aliens were using services less than expected.

In addition, States have experienced some delays in setting up mechanisms to determine what costs they actually are incurring in existing programs. Likewise, setting up new educational programs for newly legalized aliens took States longer than expected. As these matters are resolved, some acceleration of drawdown likely will occur this fiscal year. The Administration's budget request provides sufficient funds to allow States to draw down funds in FYs 1990, 1991 and 1992 at double the FY 1989 rate and still have funds available in FYs 1993 and 1994.

Question. Of the $1 billion available for FY 1991, how much will go to the States, and how much do you estimate will be spent?

Answer. Under current law, the amount appropriated is $1 billion minus the "Federal offset." (The Federal offset is the Federal share of providing certain Federal entitlement program benefits to certain categories of newly legalized aliens.) The Administration's estimate for the Federal offset in FY 1991 is $160 million. Thus, absent Congressional action to the contrary, $840 million would be appropriated for that year under current law. Of that amount, $1.5 million will be used for Federal administration of SLIAG. The remaining $838.5 million would be available for grants to States.

We believe that States will not draw down more than $600 million - the amount in the President's budget. Most SLIAG funds are used to reimburse costs incurred in ongoing public assistance and public health programs. The extent to which States incur costs in these programs depends on the extent to which newly legalized aliens access services. So far, they have accessed these programs at rates lower than those expected by States or the Federal government. This fact, coupled with declining enrollments in SLIAG-funded adult education classes, casts some doubt on both the extent to which legalization has impacted States and on States' ability to expend the funds made available under current law.

Question. Can you provide a breakdown of expenditures on public assistance programs, public health assistance, and education?

Answer. We do not yet have comprehensive actual cost figures from States. Based on States' estimates in their FY 1988 and 1989 applications, States expected to incur 59 percent of their reimbursable costs in public assistance programs, 9 percent in public health assistance programs, and 29 percent in providing educational services to newly legalized aliens. The remaining 3 percent would be expended for administrative costs. (Note: Actual costs for public assistance programs have generally been significantly lower than States' estimates. Thus, the pattern of actual costs, once established, likely will be different from that indicated by States' estimates.)

Question. I understand that you are proposing a cut of $537 million in 1991 in the SLIAG program. Can that be made without negatively impacting the States?

Answer. Congress' intent in enacting SLIAG was to provide a measure of fiscal relief to States with respect to costs they might incur as a result of the Federal decision to legalize aliens previously residing illegally in the U.S. The Administration's budget request reflects its conclusion that this purpose can be accomplished at an appropriation level lower than what Congress provided for in 1986. The budget request means that a total of over $2.4 billion will be made available to States -- $1.9 billion more than States have spent to date.

The amount requested underscores the Federal commitment to provide fiscal relief to States. Further, because of the reduction in the Federal offset last summer and lower Medicaid costs, States now have over $1 billion more in Federal, State and local funds available than they expected to have when SLIAG was first implemented. The budget request will not impinge on newly legalized aliens' ability to receive public assistance, public health, and educational services for which they are eligible on the same basis as other legal residents and citizens.

LACK OF CHILD CARE

According to press reports, State officials are concerned about their ability to enroll welfare mothers in the new, $800 million JOBS program, due to lack of quality child care facilities. The law requires that everyone enrolled in the JOBS program be provided child care, if it is needed.

Question. What is being done to insure that adequate child care is available for participants in the JOBS program?

Answer. The JOBS final rules require each State agency to guarantee child care for AFDC recipients to: (1) accept or maintain employment, or (2) participate in an educational or training activity under JOBS. The child care guarantee is limited to those families with dependent children under 13, or older children who are physically or mentally incapable of caring for themselves.

States may provide the care through a variety of methods, including: (1) provide the care itself; (2) arrange care through public or private providers by use of contracts or vouchers; (3) prepay the caretaker relative in advance for child costs through cash or vouchers; (4) reimburse the caretaker relative for expenses incurred; (5) arrange for non-reimbursed care through other agencies and community volunteer groups; (6) use the earned income disregard; or (7) use other methods the State IV-A agency deems appropriate. States must inform FSA, via a Supportive Services plan complementing the JOBS plan, which methods will be used to provide child care under the JOBS program. We are working with the States as they develop and implement their JOBS program to ensure that these requirements are met.

Question. If Congress passes the Act of Better Child Care (ABC), how long would it take to implement the child care State grants program? How would the ABC legislation be coordinated with the JOBS child care program?

Answer. Congress has not yet enacted the Act for Better Child Care (ABC) and the current House and Senate bills are very different. Without knowing about the specific requirement which might become part of the child care state grants program, it is not possible to say at this time how long the implementation of this provision would take. If such legislation passes, however, the Department will work to insure that the legislation is coordinated with other relevant programs including JOBS.

Question. Why can't the JOBS program be utilized to train public assistance recipients to be providers of child care services?

Answer. States may elect to include training of this nature under their capped JOBS program funding. In fact, we would consider this to be a very appropriate activity since, under the Act, education and training must focus on employment which is either currently available or expected to be available when training is concluded.

Question. Who would best administer the ABC program: The Family Support Administration or the Office of Human Development Services?

Answer. Congress has not yet enacted the Act for Better Child Care (ABC) and the current House and Senate bills are very different. If and when a final bill is enacted, HHS would determine which of its operating divisions is best equipped to run the program, based on its final structure.

MEASURING SUCCESS OF JOBS PROGRAM

The JOBS program requires States to enroll 7 percent of their welfare caseload in FY 1990, rising to 20 percent in FY 1995. But, it says very little about the types of job training to be provided--from hamburger flipping to valuable skills that pave the way for better jobs.

Question. How do you propose to measure the success of the JOBS program? Will a fast-food job be considered just as good a placement as a computer technician?

Answer. As part of the JOBS evaluation contract, we will look at the question as to how to measure the success of the JOBS program. Consistent with the purpose of JOBS, one factor would be the prevention of long-term welfare dependency. However, we will also look at the general impact of JOBS on earnings, income levels, welfare benefits, poverty, and educational attainment. We expect to use this research in designing performance standards for the JOBS program.

Under the JOBS program, appropriate employment goals are determined on an individual basis through the assessment and employability process. They reflect a variety of factors, including labor market conditions, individual needs and circumstances. Our regulations provide States with the flexibility to set employment goals which they feel are most appropriate based on these considerations.

Question. How long will it take to develop performance standards to measure achievements of the JOBS program?

Answer. The Family Support Act requires the Secretary to submit his recommendations for performance standards to Congress no later than October 1, 1993.

START-UP OF JOBS PROGRAM

Nearly half the States have not yet developed approved JOBS programs. as required by the 1988 Welfare Reform Act.

Question. Do you expect all States to have approved programs in operation by the October 1, 1990 deadline?

Answer. To date, 27 States have implemented JOBS programs. At this point we believe that all of the remaining States will be able to implement JOBS programs by the October 1, 1990 deadline.

Question. What problems are States encountering in setting up job training programs for welfare recipients?

Answer. No special problems have been brought to our attention. Most of the States that have implemented JOBS have operated other IV-A work programs and thus can draw upon that experience.

However, the Family Support Administration is initiating a JOBS field review program that will allow us to identify problem areas for which technical assistance would be desirable. These reviews also will identify "best practices" that can be disseminated to assist States in improving their JOBS programs. The review process will begin this spring.

REFUGEE ASSISTANCE

Question. As of January 1, 1990, Federal reimbursement of the nonfederal share of Aid to Families with Dependent Children (AFDC), Supplemental Security Income (SSI), and Medicaid was reduced from the first 24 months to the first 4 months after a refugee's entry. How have the States reacted to this?

Answer. At a national meeting of State Refugee Coordinators, convened by the Office of Refugee Resettlement (ORR) in November 1989, ORR discussed the options available for the use of cash and medical assistance funds, given the anticipated appropriation of $210 million for this purpose for FY 1990, and invited States to submit their comments and recommendations. Seven States responded to the invitation: 6 States favored the policy subsequently adopted of continuing to provide Federal refugee funding for 12 months from a refugee's date of arrival in the U.S. for refugee cash assistance (RCA) and refugee medical assistance (RMA) and of providing Federal refugee funding for 4 months from a refugee's date of arrival for AFDC/SSI/Medicaid; 1 State favored a policy which would have provided an equal duration of funding for all of these programs, estimated at 7 months from a refugee's date of arrival in the U.S.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Question. The recent very cold weather and energy price increases have put a strain on the availability of Low Income Home Energy Assistance [funds]. Can you quantify this?

Answer. Warmer weather in January made up for a colder December, and the National Weather Service predicts a normal number of heating degree days for the nation as a whole for the winter heating season, with no region more than 2 percent colder than normal. Since less than a quarter of eligible households use fuel whose prices had abnormal increases in December, season-average prices should be no more than 5 percent above October expectations. Weighted average fuel oil prices are expected to be 14 percent above October expectations. Regions using more fuel oil and propane were affected more than States depending on other fuels.

Sources: * The National Weather Service

* Department of Energy, Energy Information Administration (report: A Short-Term Analysis of Heating Fuel Market Behavior, January 31, 1990)

Question. How much have home energy prices increased for the hardest hit?

Answer. The New England, Mid-Atlantic and Midwest regions of the country experienced the biggest increases in residential fuel prices. The biggest increases occurred in the price for heating oil and propane.

Average heating price increases for all fuels for the period October 1, 1989 to March 15, 1990 are expected to be as follows:

Region	Increase 10/1/89 - 03/15/90
United States	4-5%
New England	9%
Mid Atlantic	7%
East North Central	3%
West North Central	4%
South Atlantic	5%
East South Central	4%
West South Central	2%
Mountain	2%
Pacific	1%

Sources: * Department of Energy
* Bureau of the Census

Question. Have applications for assistance increased markedly? Where do you see the greatest problems for the States?

Answer. The FY 1990 Winter Telephone Survey conducted by the Office of Energy Assistance asks the States for information about applications for LIHEAP heating and crisis assistance (approved and denied) for the 3-month period from October 1 to December 31, 1989. The surveys have just been completed, and the information is currently being compiled and analyzed.

Based on preliminary information from the surveys, nationwide there appears to have been a decrease in the number of heating assistance and crisis assistance applications received in the first three months of FY 1990, compared to the same period last year. For the heating assistance program, 22 States have reported increases in the number of applications they have received in the first three months of FY 1990, compared to the same period in FY 1989. 26 States have reported decreases in the number of applications. (Data is incomplete for 3 States.) For the crisis assistance program, 20 States have reported increases in applications, while 15 States have reported decreases.

Of those States which have indicated a significant increase in the number of applications, about half of them have indicated that the increases were due to the unseasonably cold weather in December and the dramatic rise in fuel prices.

Question. If a 1990 supplemental appropriation for LIHEAP is judged necessary in light of recent events, do you have any position on special conditions that might be attached to it, including whether the formula for distributing money among the States be modified?

Answer. If Congress passed a supplemental appropriation without special instructions, the Department would distribute it according to the LIHEAP statute's allocation formula, and grantees would expend it according to the LIHEAP statute's current requirements. With a total appropriation of $1.975 billion or less, the statute and legislative history require that LIHEAP funds be allocated among the States according to the formula used in fiscal year 1984. The Department does not support a supplemental appropriation for LIHEAP and has no position on possible special conditions.

BUYERS COOPERATIVES FOR LIHEAP

A number of private organizations have formed cooperatives to negotiate reduced heating oil prices from local suppliers. Savings can be considerable, in the range of 10 to 25 percent.

Question. How many States have negotiated special lower fuel prices for payments through the Low Income Home Energy Assistance Program?

Answer. Some states are negotiating with home energy suppliers to provide discounts for LIHEAP fuel purchases. However, we do not collect information on how many states negotiate discounts for payments through LIHEAP. Nor are we aware of such data being collected nationwide by other parties.

Question. What can be done nationally to get States to further take advantage of discount pricing?

Answer. Under the block grant, LIHEAP grantees have primary responsibility for administering the program. Using the LIHEAP statute's technical assistance and training discretionary authority, the Department supports an annual energy assistance conference and a LIHEAP clearinghouse to disseminate information on innovative and successful practices, including use of LIHEAP funds to leverage additional funds or benefits such as discount prices. We plan to sponsor a roundtable on leveraging in fall 1990.

CHILD SUPPORT ENFORCEMENT PROGRAM

Question. In the last year, administrative costs went up 18 percent in the child support enforcement program. This is nearly double the increase from the previous year. Why are State administration costs increasing so rapidly?

Answer. State administrative costs are rising for a variety of reasons. The staffing of State and local support enforcement agencies has been growing steadily. Expanding automation carries an additional cost as agencies develop new systems or enhance existing systems, and then convert their operations to the new way of doing business. Pay raises for State and local government employees impact both direct and indirect costs of the Child Support Enforcement program. And, the transfer of ongoing child support cases into the IV-D program, which is responsible for at least part of the rapid growth in non-AFDC collections, has been accompanied by federal matching for administrative costs which were previously borne entirely by State and/or local government.

From a historical perspective, the recent sharp year-to-year increase in administrative costs is not without precedent. A similar situation prevailed around the time of enactment of the Child Support Enforcement Amendments of 1984. Indeed, given the demands inherent in the child support provisions of the 1988 Family Support Act - especially prompt State standards regulations, periodic review and modification requirements, and paternity establishment standards, it is likely that administrative costs will continue to rise at least for the next several years.

Question. What can be done to control state administrative costs?

Answer. Federal funding for child support enforcement administrative costs is, by statute, an open-ended entitlement program. Within this context, the Administration is seeking to restrain administrative costs through our legislative proposals to limit Federal funding for States that are inadequately pursuing support on behalf of AFDC recipients and to shift the cost of support enforcement services from the taxpayer to those beneficiaries of program services who are financially capable of paying for them.

A balance between controlling costs and needed program expansion must be carefully crafted. The statutory goals of the child support program are to insure that children are supported by their parents, to foster family responsibility, and to reduce the cost of public assistance to the taxpayer. As shown by program audits, many States are operating support enforcement programs that are not in full compliance with federal requirements. The Family Support Act of 1988 vastly increases these requirements. From all indications, the potential payoff from vigorous use of the tools and techniques now being required will be higher child support collections for families in financial need and a quantum leap in the number of paternities established for children born out-of-wedlock. Building a truly effective and efficient support enforcement program all across the country will require both time and an upfront investment of resources for a longer term payoff.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Question. What capacity for supplementing LIHEAP appropriations do you expect States to have in fiscal years 1990 and 1991?

Answer. States would increase LIHEAP funds by roughly 20 percent, if they used their authority to transfer funds from other block grants. About $3.9 billion has been distributed to the States in oil overcharge funds from FY 1981 to date. This includes the $2.1 billion distributed under Exxon and the $1.2 billion so far distributed under Stripper Well.

The States have designated virtually all Exxon funds for program projects. Of the $1.2 billion so far distributed under the Stripper Well agreement, $247 million remains undesignated and still available to the States. These funds may still be spent in approved program areas including low income home energy assistance. Funds designated for future use in other programs could be redesignated for LIHEAP.

In addition, States can expect to receive approximately $350 million in FY 1990 and $100 million in FY 1991 in oil overcharge distributions, mainly from the Texaco settlement. According to the schedule of Texaco distributions, approximately $76 million will be released to the States on March 1, 1990. About $10 million in other Stripper Well funds has already been distributed in FY 1990. Therefore, States will already have a total of $86 million of the $350 million expected in FY 1990.

States have the discretion to use any or all of these funds for their LIHEAP programs.

Question. How much do you judge States able to commit to LIHEAP from previously distributed oil price overcharge funds?

Answer. The States and territories have discretion over which programs receive oil overcharge funds, how much the program receives, and when they expend the funds. The Exxon case limits the States' discretion to LIHEAP and the four DOE energy conservation programs, but the Stripper Well agreement gives the States much wider discretion.

The Department of Energy, not HHS, monitors the distribution and obligation of oil overcharge funds by the States. However, based on the most recent information from DOE, we have been informed that proposals involving all $2.1 billion of Exxon funds have been designated for past or future use by States for either LIHEAP or the four DOE programs. DOE indicates that $502 million of Exxon funds are designated for LIHEAP (24%), but so far our State LIHEAP offices report that $425 million in Exxon funds have been expended through LIHEAP from FY 1986 to FY 1989 (about 21%).

For Stripper Well funds, DOE indicates that States have submitted proposals totaling $1.1 billion. Not all of these proposals have been approved, and some have actually been rejected. Of the approved plans, about $90 million has been earmarked for LIHEAP (8%). Approximately $113 million in Stripper Well funds has been reported to HHS by State LIHEAP offices from FY 1986 to FY 1989 (about 11%).

There currently are $247 million in undesignated oil overcharge funds and an additional $350 million in FY 1990 and $100 million in FY 1991 estimated to be distributed to the States. The States will decide how much of these additional funds will be designated for LIHEAP. States can also redesignate funds from other programs to LIHEAP.

Question. What new oil price overcharge disbursements do you anticipate will become available this year and next?

Answer. Based on our communications with DOE, approximately $350 million will be distributed to the States in FY 1990, and approximately $100 million is expected for distribution in FY 1991. Stripper Well funds account for most, if not all, of future distributions.

The Department of Health and Human Services does not control and cannot predict the date of actual distribution of additional oil overcharge funds. The Department of Energy is the source for information and estimates regarding the amount and distribution schedule of future settlements. It should be noted that these amounts are estimates and could vary significantly since these funds are generated by court orders and voluntary settlements, which are not controlled by either DOE or HHS.

Question. Have States shown any movement toward increasing the degree to which they commit oil price overcharge monies to LIHEAP?

Answer. We have not seen an overall increase in the percentage of oil overcharge funds being designated by the States for their LIHEAP programs. Most new funds are stripper well funds and States are designating a lower percentage of stripper well funds for LIHEAP. We assume this reflects State priorities.

Question. Both the Low Income Home Energy Assistance legislation and the Community Services Block Grant law expire at the end of FY 1990. The Refugee Act has already expired. What is the status of Administration proposals to renew these expiring authorizations?

Answer. The President's budget seeks funding of $1.05 billion for the Low Income Home Energy Assistance Program in fiscal year 1991. The Department has several suggestions to improve LIHEAP program administration. We summarized three of these suggestions during the February 1 LIHEAP reauthorization hearing held by the Human Resources Subcommittee of the House of Representatives Education and Labor Committee.

The Department is not proposing reauthorization for the Community Services Block Grant. Given the demand for Federal budget deficit control and the recent expansion of such entitlement programs as welfare reform employment services and child care, the Department does not believe that the limited Federal funds available should be expended on this program. While we do not contend that there is duplication of CSBG services with other Federal programs, we do show evidence that some of these services are provided in other Federally funded program areas, e.g. the Social Services Block Grant and certain HUD programs. The Department is proposing to reauthorize the Refugee and Entrant Assistance program.

FEDERAL LOSS IN CHILD SUPPORT PROGRAM

In recent years, the child support program has more than paid for itself, with collections more than offsetting administrative costs. However, the Federal government has sustained bigger and bigger losses, while the States have increasingly profited.

Question. In view of the need to reduce the national budget deficit, why should the Federal government continue to so heavily subsidize the States in the child support program?

Answer. The child support enforcement program is vital to the well-being of American children--more than 15 million of whom are now living in single-family households, mostly headed by women. Recent statistics show that more than 40 percent of families headed by single women are living below the poverty line. We believe that the Federal government must continue to ensure that these vulnerable poor families have access to child support services, both to increase their level of self-sufficiency and to reduce their reliance on Federal and state welfare programs.

Congress and the Administration have addressed the needs of these families through passage of the Family Support Act of 1988. This legislation takes a significant step in helping welfare families attain self sufficiency. Themes in this legislation include the mandatory use of guidelines in setting support orders, tightening of paternity establishment requirements, the use of immediate wage withholding at the time a support order is established, and automation in all States by October 1, 1995.

With the full implementation of this landmark legislation, great progress will be made in making states more efficient and effective in their programs and parents more responsive to their obligations.

From its inception in 1975, the child support enforcement program made money for the taxpayer while showing a net cost for the Federal Government, and net savings for the States. In FY 1989 there was also a net loss to the taxpayer. In FY 1992 and thereafter, we expect the taxpayer to again realize a positive return from the child support enforcement program. The savings to the taxpayer will continue to be smaller than it ought to be, however. For this reason, we are proposing legislation to stimulate greater efficiency and effectiveness on the part of State child support enforcement agencies, and to have those who benefit from support enforcement services bear a greater share of the costs, consistent with their ability to pay. These measures will also reduce Federal program losses.

Finally, in looking at program costs, one must also address program benefits, not all of which are quantifiable. Studies show that non-AFDC child support collections avoid costs that would, in their absence, be otherwise borne by the AFDC, Food Stamp and Medicaid programs. This cost avoidance value, which is not reflected in the Federal Budget, has been roughly calculated at 20 cents for every dollar of non-AFDC collections. Paternity establishment is both a statutory goal and a social benefit of the support enforcement program, but one that is not reflected in the "bottom line" of budget costs or savings to the Federal Government. And, as pointed out in the recent Congressional Research Service study of child support enforcement, program activities such as paternity establishment, location and establishment of a support order all have to be viewed in an actuarial context. That is, they are immediate cost items, which are reflected in the budget for a given fiscal year, but they are also inputs that can, and increasingly will, generate a stream of income in the form of collections that will commence later and continue for many years into the future.

Question. What proposals do you have to reduce the Federal loss from the child support program, without adversely affecting state incentives to enforce the law?

Answer. We are proposing a new method to promote increased program efficiency and effectiveness.

This proposal would mandate that State Child Support Agencies collect a dollar on behalf of AFDC families for every dollar of matching funds the Federal government pays for child support activities on behalf of both AFDC and Non-AFDC families.

Federal matching funds for administrative costs would be capped at the total amount of collections on behalf of AFDC families for these States whose AFDC collections do not at least equal the total costs for child support activities on behalf of both AFDC and Non-AFDC families. After FY 1991, the cap on federal administrative matching funds for the States that do not meet this criteria would be reduced each year until FY 1999. This proposal will motivate States to improve their services in the collection of AFDC support payments.

Another legislative proposal would require States to modify the non-AFDC application fee, basing it on a sliding scale according to income level and waiving it for low-income families. It will also require cost recovery for services rendered to both AFDC and Non-AFDC cases. Both parents will be required to pay for these successful services, but the amount will be based on income and custodial parents will only be assessed after the current child support obligations have been met. This proposal would ensure access to child support services for those families that might not otherwise be able to collect child support, while providing for fees and cost recovery for individuals able to pay for such services.

Question. What impact would greater reliance on user fees, from those who could afford to pay, have on increasing the quality of child support enforcement services?

Answer. The Administration is proposing a mandatory sliding scale application fee for non-AFDC child support services and an income-tested approach to recovery of support enforcement costs in excess of the application fee. The proposals are carefully designed to accommodate the ability to pay for services, and to facilitate access to the Child Support Enforcement Program.

Adoption of income tested application fee and cost recovery proposals would remove financial barriers that now deter some low income families from seeking needed support enforcement services. By the same token, they will eliminate financial incentives that presently encourage higher income families to obtain support enforcement services from government at the taxpayers' expense rather than from the private sector. By charging those who are financially capable of paying for all or a portion of the cost of services they utilize, State and local support enforcement agencies will be better able to target their resources on families who cannot afford to pay them.

Question. What are your long-term projections for reducing the Federal deficit in this program?

Answer. Even with the Administration's proposal, the Federal deficit will continue to increase. Under our legislative proposal, the deficit - $499 million in FY 1990 - would be $680 million rather than $800 million in FY 1995. State profits would continue to grow. The key to increasing the program's financial return to both the taxpayer and to the Federal Government is rapid and vigorous implementation of existing federal legislation, i.e., the Child Support Enforcement Amendments of 1984 and the Family Support Act of 1988. The tools and techniques provided here and in accompanying Federal regulations give State and local support enforcement agencies the wherewithal to vastly increase collections and to operate much more efficiently. This, in turn, directly translates into a more favorable "bottom line."

The President's Budget assumes that States will move aggressively to improve their performance. Starting slowly in FY 1991, legislative features such as mandatory guidelines for setting support order amounts and immediate wage withholding as well as administratively promulgated standards for program operations will result in higher collections and greater operational efficiency. The direct payoff rises significantly in the years after 1991.

After a two or three-year hiatus, child support program savings to the taxpayer are expected to resume in FY 1992 (and perhaps as early as FY 1991), and to rise significantly over the next few years. The new legislative proposals, which are part of the President's Budget, will favorably impact on the net savings projection while also serving to reduce the Federal deficit otherwise expected under current law.

Question. Fewer than half of fathers not living with their kids pay anything toward their keep. An estimated $4 billion in potential child support payments currently goes uncollected, every year. Why is there such slow progress in improving child support collections?

Answer. We do not agree that the progress made in collecting child support has been slow, but this Department, like the Congress, would like to see even faster progress. For example, from 1979 to 1987, the number of never married families has almost doubled from 1.4 million to 2.6 million families. In 1979, only 145,000 of such families had child support awards. In 1987, 517,000 never married families have child support awards--an increase of over 350 percent. The efforts of the child support program on behalf of AFDC families is largely responsible for the increase in the proportion and number of never married families with awards. We believe that the provisions in the Family Support Act, providing increased matching for genetic testing and establishing more stringent paternity establishment standards will increase the programs efforts even further.

Total collections in FY 1991 are projected at approximately $6.8 billion, an increase of over 15 percent from 1990. Total projected collections will more than double, just between 1986 and 1991. These collections represent the collection of current support on behalf of some two million families annually. Just as importantly, they also represent the collection of uncollected support owed to families from prior years. The Federal and State tax off-set program alone in FY 1989 made possible the collection of a half billion dollars in past due child support--support which would not have been collected without the child support enforcement program.

Full implementation of the Family Support Act should produce a marked increase in support collected. Provisions, such as mandatory guidelines, periodic review, and modification of orders should increase the amount of child support due. State implementation of immediate wage withholding should increase the amount of support paid. Additionally, the prompt State standards regulations and increased automation should reduce case processing time both in establishing awards and in insuring that collections are made. Each year increasing numbers of children spend some part of their lives in a single parent family; as that number grows, the child support enforcement program has to work more efficiently and effectively to insure that the nation's most vulnerable children have access to the financial support they need from both parents.

Question. Some localities are publishing "10 most wanted" lists of parents delinquent in child support payments and are apparently meeting with considerable success in making long-overdue collections. What are you doing to encourage greater use of such innovative child-support collection techniques?

Answer. We continue to support financially and to laud innovative State techniques. When such approaches prove successful, they are highlighted in the many information-sharing activities sponsored by the Office of Child Support Enforcement, including Informational Memoranda, and "The Child Support Report". We disseminate such publications in order to insure their accessibility to the widest possible audience.

FEDERAL EMPLOYEES OWING CHILD SUPPORT

The Inspector General's Office has reported that about 70,000 Federal employees are in arrears on child support payments totaling $269.4 million. The Inspector General's office estimated child support collections could be increased by as much as $23 million annually and recommends that the Family Support Administration make its computer intakes available to the states.

Question. What have you done to implement the inspector general's recommendations?

Answer. OCSE has taken a number of steps to implement the Inspector General's recommendations. OCSE very promptly distributed the results of the computer match to the State child support agencies for their use in implementing wage withholding where appropriate. At OCSE's urging, the Office of Personnel Management (OPM) has updated its listing of Federal agents designated to accept legal process. This was done as an appendix to regulations issued by OPM at 5 CFR 581, on January 16, 1990, and we have disseminated this revised listing to State and local offices for their use in initiating withholding orders against the wages of Federal employees.

We are monitoring on a quarterly basis the progress of selected States in pursuing delinquent cases identified by the match. During the quarter ending December 31, 1989, Maryland had begun action on 496 of its 3,947 delinquent cases. Virginia made a quicker start, and acted on 1,370 of its 3,154 cases. In examining the 1,370 cases, Virginia found that 581 cases already had withholding orders in effect. Through the end of December, 213 withholding orders have been issued following the match. Another 156 obligers were found to be no longer employed by the agency and the new employer was unknown. Withholding was not requested in another 420 cases for a variety of reasons. In the District of Columbia, action has been taken on 532 delinquent cases identified there. Some 117 cases already had withholding orders in effect prior to receipt of the computer match results. New withholding orders were initiated in 373 cases. And in 42 cases, wage withholding orders were not requested for a variety of reasons including termination of employment.

After further experience, OCSE will evaluate the value of subsequent tape matches, as recommended by the Inspector General.

RECOMMENDATIONS FOR CHILD SUPPORT SAVINGS

The latest semi-annual Inspector General's report estimates the Family Support Administration will save $570 million by requiring the States to periodically review child support orders and revise them on the basis of an absent parent's ability to pay.

Question. Have you fully implemented this recommendation?

Answer. The Inspector General's recommendation is embodied in the Family Support Act of 1988. That legislation requires that States establish mandatory presumptive guidelines for setting child support awards. By October of 1990, States must be able to review and modify support orders when requested to comply with their guidelines. And by the end of 1993, States must establish a periodic review and modification of child support orders at least every 36 months.

Implementing regulations are now proceeding through the clearance process, and OCSE is providing technical assistance to the States in carrying out these new requirements. In addition, also as mandated by the Family Support Act, we have funded four demonstration projects to evaluate model procedures for reviewing child support orders. These projects in Delaware, Illinois, Colorado and Florida supplement an earlier OCSE-funded project already underway in Oregon.

Question. Do you agree with the Inspector General's estimates of savings?

Answer. We worked with staff from the Inspector General's office in evaluating the estimates contained in their report entitled, "Child Support Enforcement Collection for Non-AFDC Clients." They used Wisconsin's guidelines to estimate potential increases in support orders and their estimates were in the range of $115 to $127 million annually. We do not know where the $570 million figure comes from.

Question. What savings will be realized by the Federal government in fiscal 1991 by carrying out this recommendation?

Answer. There are no separate estimates of the impact of periodic review and modification of orders from either the Administration or the Congressional Budget office. The provisions for mandatory guidelines will produce more money in collections as a result of both new and modified orders. Our budget estimates indicate that in FY 1991, mandatory guidelines will increase AFDC child support collections alone by $69 million.

Question. Are these savings reflected in your fiscal 1991 budget request?

Answer. Yes they are.

Question. What actions will be taken to monitor States' compliance?

Answer. Child support enforcement staff in the regional offices of the Family Support Administration regularly monitor State compliance with Federal requirements. They periodically enter information into a centrally-maintained Legislative Tracking System that allows OCSE to assess the progress of necessary State enabling legislation for these and other provisions of the Family Support Act. Delays or lack of progress in State implementation can trigger appropriate notification from OCSE, with the ultimate penalty being loss of all federal funding under Title IV-D for failure to have an acceptable State plan as required by federal statute.

Once a State has adopted any necessary legislation, regulations and/or court rules, we monitor actual use primarily through recurring program audits. Title IV-D mandates that OCSE audit State programs no less frequently than once every three years. A finding of noncompliance with federal requirements subjects the State to a financial penalty varying from one to five percent of the federal share of AFDC matching funds.

POOR FINANCIAL MANAGEMENT

GAO has called for government-wide improvements in financial management systems. There are reportedly billions of dollars of differences between balances recorded in accounting systems and financial reports.

Question. What is your assessment of weaknesses in financial management of your agency?

Answer. The weaknesses in financial management at the Department of Health and Human Services can be directly attributed to the antiquated financial systems currently in place. These systems are labor-intensive, relying heavily on manual processing and report preparation. Also, they are not properly linked to one another (e.g., procurement and core accounting). These deficiencies have led directly to the reconciliation problems recently reported by GAO.

Question. What specific areas could be strengthened, and what is your plan for making improvements?

Answer. Improvement of financial management systems is a major HHS initiative. The Department is implementing the Phoenix Project, which is aimed at strengthening HHS financial management systems by:

- continuing to improve and standardize budget and financial information systems and processes for greater operating efficiencies and control;
- consolidating financial information into an agency-wide perspective as required by OMB Circular A-127;
- implementing the Federal government's Standard General Ledger in HHS;
- modernizing our automated financial management systems and those administrative management functions which provide data to Financial Management; and
- further improving compliance with OMB/GAO requirements and the Federal Managers' Financial Integrity Act.

The HHS plan addresses the need for the timely implementation of actions to address these priorities as they affect automated systems, whether wholly within the Phoenix structure (e.g., the Operating Divisions' Accounting System) or interfacing with it (e.g., the Personnel Payroll System).

The basic concept for the Phoenix Project derived from the Federal government's Reform '88 initiative, which sought to reduce inefficiencies in the operation of governmental administrative and financial systems, and to promote improved decision-making, accountability, and system integrity controls.

Question. Do you agree with GAO's assessment that managers need more and better training in Financial Integrity Act issues?

Answer. The Department agrees that training is a key element in implementing an effective FMFIA program. In this respect, the Chairman of the Council on Management Oversight has already requested HHS' Assistant Secretary for Personnel Administration to develop a comprehensive, Departmentwide FMFIA training program. In addition, the Director of the Department's FMFIA Program has been working with the Office for Civil Rights and the Family Support Administration in a separate effort to train their staffs under the auspices of the Office of Personnel Management.

GENEROUS FEDERAL MATCHING IN CHILD SUPPORT ENFORCEMENT

The Child Support Program provides that welfare mothers get a $50 monthly bonus over their public

assistance benefits, from collections from non-custodial parents. Remaining collections are split between State and Federal governments. Yet, the Federal government reimburses States for 66 percent of administrative costs, and pays additional incentive payments for high performance on top of this. With Federal matching grants and incentive payments, States and localities only paid 14 percent of administrative costs in FY 1989.

Question. Does Federal funding need to be so generous to make this program work?

Answer. We do not know the effect on State behavior of changing the Federal financing structure of the Child Support Enforcement (CSE) program. When the authorizing legislation was passed in 1975, it was felt that States needed substantial inducements to undertake the development of a child support enforcement program. CSE programs are now firmly established in most States. Discontinuation of services would be unlikely in most States both because of the general acceptance of the importance of child support in reducing or preventing welfare dependency and because the provision of child support services is also tied to the States' Federal AFDC funding. Our current strategy is designed to create disincentives for inefficient State operations while continuing to maintain a generous funding structure for States which perform in a cost efficient manner. In particular, we believe that the threat of reduced reimbursement as outlined in our program efficiency proposal will motivate inefficient States to improve their performance.

Question. How much would the Federal deficit be reduced for each one percent reduction in Federal matching funds?

The following table assumes no cutback in the level of program services, and shows the impact on the federal deficit for each one percentage point reduction in the matching rate, using FY 1989 as an illustrative year. Even with a considerably lower Federal matching rate, States would continue to experience net savings.

Federal Matching Rate	Federal Share of Admin Costs	Net Federal Deficit	Net State Savings
	(Dollars in Millions)		
68%	$956	$471	$369
67	942	457	355
66	929	444	342
65	916	431	329
64	902	417	315
63	889	404	302
62	876	391	289
61	862	377	275

Federal Matching Rate	Federal Share of Admin Costs	Net Federal Deficit	Net State Savings
	(Dollars in Millions)		
60%	$849	$364	$262
59	835	350	248
58	822	337	235
57	809	324	222
56	795	310	208
55	782	297	195
54	769	284	182
53	755	270	168
52	742	257	155
51	728	243	141
50	715	230	128

Question. Child support payments could obviously be improved by increasing employment opportunities for jobless absent parents. What is being done to link the Child Support Program together with the JOBS program?

Answer. Section 482(d)(3) of the Social Security Act requires the Secretary to grant waivers to no more than five States to allow them to provide services to non-custodial parents. We are working on a Federal Register notice to be published this spring announcing the availability of the waivers and requesting interested States to apply.

NON-WELFARE CASES IN THE CHILD SUPPORT PROGRAM

Under current law, the Federal government pays 66 percent of State costs to provide child support enforcement services for non-AFDC cases. In addition, States also get non-AFDC incentive payments from the Federal.

Question. If states had to pay a greater share of the cost of administering non-AFDC child support enforcement, would there be a greater incentive for them to recover costs from parents?

Answer. A reduction in the Federal match need not necessarily create incentives for cost recovery. The decision to recover costs from non-AFDC parents is not a function of the Federal-State match rate. A few States recover costs from the custodial parent; this is a simple procedure but raises questions of equity. The Administration's proposal will address the problems of costly recovery procedures and equity in order to make cost recovery a more viable process for States. We believe these changes would enhance States' willingness to recover costs at the current FFP rate.

Question. Why shouldn't administrative costs be recovered from non-custodial parents on a sliding scale basis?

Answer. We agree that administrative costs should be recovered from non-custodial parents on a sliding scale basis. This provision will be included in the Administration's fee and cost recovery legislative proposal.

JOBS SPENDING

Last year, you requested that JOBS funding be limited to $350 million for FY 1990, instead of the $800 million provided for by statute.

Question. How much do you estimate will actually be utilized by States in the FY 1990 JOBS program?

Answer. Based on the data we have available, the FY 1990 estimate for JOBS and WIN transitional funding is $463,038,000.

Question. Provide a state-by-state spending estimates for both FYs 1990 and 1991.

Answer. Attached is a state-by-state spending estimate for JOBS and WIN transitional funding for FYs 1990 and 1991.

Payments to States for Family Support Activities
Federal Share of Grant Award Obligations

State and Local Jurisdictions	FY 1990 Estimate 1/	FY 1991 Estimate
Alabama	$ 1,862,111	$ 10,471,590
Alaska	864,976	2,122,063
Arizona	643,162	7,768,683
Arkansas	4,470,295	5,581,083
California	123,445,822	154,955,066
Colorado	6,535,589	9,936,904
Connecticu	8,241,290	10,144,071
Delaware	1,599,863	1,947,501
Dist. of Col.	2.013,446	3,735,294
Florida	14,000,000	23,242,297
Georgia	14,000,000	20,297,778
Guam	67,327	427,847
Hawaii	531,753	4,158,479
Idaho	623,780	2,448,476
Illinois	10,655,745	58,382,808
Indiana	5,543,393	13,496,355
Iowa	6,000,000	10,524,329
Kansas	5,370,423	6,688,925
Kentucky	946,996	13,681,806
Louisiana	663,256	20,613,607

Payments to States for Family Support Activities
Federal Share of Grant Award Obligations

State and local Jurisdictions	FY 1990 Estimate	FY 1991
Maine	514,408	5,335,032
Maryland	13,508,512	16,809,779
Massachusetts	19,683,910	24,292,359
Michigan	25,695,357	64,962,486
Minnesota	12,767,940	16,890,932
Mississippi	689,784	13,569,375
Missouri	3,642,931	18,800,891
Montana	938,510	3,104,417
Nebraska	2,500,000	3,759,065
Nevada	1,369,369	1,667,980
New Hampshire	959,555	1,167,042
New Jersey	23,389,244	28,901,312
New Mexico	916,459	5,073,897
New York	7,996,098	94,122,551
North Carolina	1,286,712	16,063,316
North Dakota	769,629	1,608,450
Ohio	39,755,611	62,642,527
Oklahoma	6,752,454	8,531,138
Oregon	2,553,945	10,300,436
Pennsylvania	17,700,000	50,074,042
Puerto Rico	553,900	14,551,571
Rhode Island	3,435,586	4,242,645
South Carolina	4,500,000	9,157,311
South Dakota	1,587,996	1,898,822
Tennessee	897,341	15,816,502
Texas	9,187,035	39,525,556
Utah	4,055,710	4,932,072
Vermont	679,022	2,763,302
Virgin Islands	243,533	343,161
Virginia	1,310,881	13,142,677
Washington	15,386,891	23,416,753
West Virginia	9,823,722	12,224,201
Wisconsin	22,353,717	28,162,873
Wyoming	660,787	1,431,008
Total	466,645,772 2/	1,000,000,000 3/

1/ Estimates reflect pre-sequester amounts.

2/ State-by-State amounts represent State estimates of expenditures. The total amount of program obligations is estimated at $463,038,000.

3/ State allocations based on available ceiling for all States in FY 1991 including $89,557 for American Samoa.

REFUGEE CASH AND MEDICAL ASSISTANCE

Federal payment of refugee cash assistance (RCA) and refugee medical assistance (RMA), available to needy refugees who meet the means test but not the family structure eligibility requirements of the major Federal programs, is being continued for the first 12 months after a refugee's entry.

Question. What percentage of refugees receive RCA and RMA, compared to those participating in the AFDC, SSI, and Medicaid programs?

Answer. The following information, as of September 30, 1989, is the latest available:

Program	Number of Time-Eligible* Refugee Recipients	Percent
AFDC	55,967	61.2%
SSI	7,427	8.1
RCA	23,651	25.9
General assistance	4,368	4.8
Total	91,413	100.0%

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* 24 months or less in the U.S.

All AFDC and SSI recipients are eligible for Medicaid, and all RCA recipients are eligible for RMA. In addition, some non-cash-assistance recipients are eligible for Medicaid only or RMA only, but data are not collected on such eligibility.

Question. What information do you have on the extent to which refugees who are initially resettled under a voluntary agency matching grant program also access Federal or Stat welfare programs, either during or after their participation in the voluntary agency program?

Answer. In 1989, the Office of Refugee Resettlement obtained data on cash assistance usage by participants in the voluntary agency matching grant program in Chicago, Los Angeles, and Philadelphia. Cash assistance records were reviewed for refugees who arrived between October 1, 1987, and March 31, 1988. The preliminary findings for those who were under age 65 at their time of arrival in the U.S. are as follows:

	Chicago	Los Angeles	Philadelphia
Percent who ever used cash assistance through 4th month in U.S. (period of matching grant)	3.2%	4.4%	0.5%

	Chicago	Los Angeles	Philadelphia
Percent who ever used cash assistance during first year in U.S. 48.1%	39.6%	43.5%	48.1%
Percent who were receiving cash assistance in their 12th month in U.S.	26.0%	39.9%	28.4%

COMMUNITY SERVICES BLOCK GRANT

Question. This program [CSBG] expires at the end of FY 90. Will you propose its reauthorization? If so, what legislative changes, if any, do you consider necessary?

Answer. The Department is not proposing reauthorization.

Question. Does the Federal Office of Community Services (OCS) coordinate the design of its programs with other related agencies? For example, what is the relationship between your Community Economic Development program and related activities administered by the Department of Housing and Urban Development or the Department of Commerce? Similarly, are your rural housing and community food and nutrition programs coordinated with the Department of Agriculture? How do you protect against duplication of services?

Answer. The Office of Community Services has no formal relationship with the other Federal agencies in question. Re duplication of services: In reviewing applications for funding under OCS discretionary programs, OCS officials take into account all other funds which will be mobilized for the proposed projects and would be aware if other funds, Federal or non-Federal, would be allocated for the specific activities for which the OCS funds have been requested. In addition, OCS requires that all of its grant funds be audited. Although we do not believe that the OCS funds are duplicating other Federal funds, it should be noted that the Department is not requesting reauthorization of these programs because evidence shows that some of the services are available through other Federally-funded programs. Services and cash grants that are provided to organizations and low-income individuals through these programs are substantially the same as those authorized by, for example, meals and food distribution programs administered by the Department of Agriculture, the Administration on Aging's nutrition programs, and the JOBS program.

AID TO FAMILIES WITH DEPENDENT CHILDREN (AFDC) JOBS PROGRAM

Estimates of the Congressional Budget Office indicate that a relatively small percent of AFDC families can be expected to leave the AFDC rolls as a result of participation in the JOBS program. To be realistic, should the Administration focus more on the goal of helping AFDC mothers become less dependent on welfare rather than totally free of welfare?

Question. Will the $350 million appropriated for FY 1990 be sufficient to fund the JOBS program (and phase out the Work Incentive (WIN) program)? Does it appear that the full authorization of $1 billion will be needed to fund the JOBS program in FY 1991?

Answer. Based on the data available, the current estimate for JOBS for FY 1990 is $463,038,000. The entitlement by law for this program in FY 1990 is $800,000,000; should funds in excess of $463,038,000 be required, these will also be available up to the $800,000,000 ceiling under the indefinite authority included with the FY 1990 appropriation to meet unanticipated needs.

The $1,000,000,000 request for FY 1991 is based on estimates of caseload projections and program participation rates. Currently, we estimate that FY 1991 outlays will total $879,662,000.

Question. As of January 1990, over half of the States had implemented their JOBS program in all or part of their State. Do you expect the rest of the States to start their JOBS program before the required date, October 1, 1990?

Answer. We anticipate that eight more States and the District of Columbia will seek approval to start their JOBS programs either on April 1, 1990, or July 1, 1990. The remainder of the States are expected to begin JOBS on October 1, 1990.

Question. How many Indian tribes or Alaska Native organizations have applied to the Secretary to conduct a JOBS program?

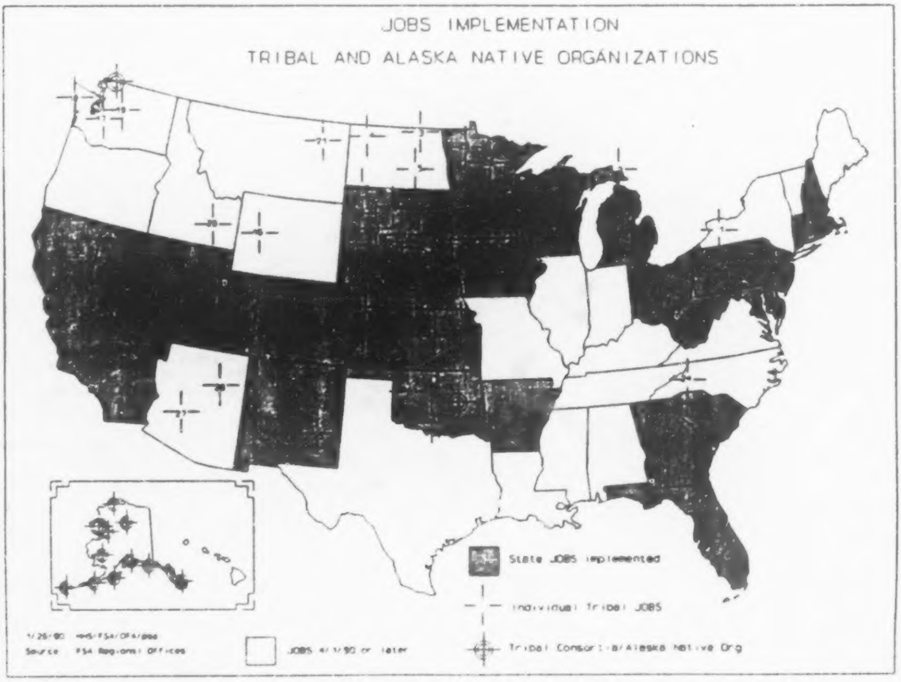
Answer. One hundred twenty five (125) tribes and Alaska Native organizations have applied.

Question. Have all of such applications been approved (if not, why not)?

Answer. The applications of 40 grantees have been approved and are operating JOBS programs. Tribes and Alaska Native organizations were required to submit their applications for JOBS by April 13, 1989 (6 months after the date of enactment of the Family Support Act). In order to comply with this statutorily required deadline, we permitted tribes and Alaska Native organizations to submit an initial application, with final documentation to be provided 45 days prior to planned implementation. We are working with these organizations as they develop appropriate JOBS programs. Tribal entities have until August 15, 1990 to provide us with final documentation for their applications.

Question. Have any of the programs been implemented?

Answer. Yes. Forty tribal entities and Alaska Native organizations have implemented JOBS. (See attached charts and maps.)


JOBS IMPLEMENTATION
TRIBAL AND ALASKA NATIVE ORGANIZATIONS
State JOBS implemented
Individual Tribal JOBS
JOBS 4/1/90 or later
Tribal Consortia/Alaska Native Org

1/26/90 HHS/FSA/OFA/pbe
Source: FSA Regional Offices

Native American Applications

Approved for JOBS Implementation

Number	Grantee	Implementation Date
1	Seneca Nation of Indians Irving, NY	10/1/89
22	The Minnesota Chippewa Tribe Cass Lake, Mn.	7/1/89
2	The Saulte-Ste. Marie Tribe Saulte-Ste. Marie, Mi.	7/1/89
14	Chicasaw Nation Ada, Ok.	10/1/89
15	Comanche Tribe of Oklahoma Lawton, Ok.	10/1/89

Number	Grantee	Implementation Date
Consortium	Inter-Tribal Council, Inc. Miami, Ok. (Eastern Shawnee, Seneca-Cayuga, Wyandot, Quapaw, Ottawa, Peoria, Miami, Modoc)	10/1/89
12	Kickapoo Tribe of Kansas Horton, Ks.	7/1/89
13	Prairie Band of Potawatomi Indians Mayetta, Ks.	7/1/89
4	Devils Lake Sioux Tribe Ft. Totten, N.D.	7/1/89
7	Standing Rock Sioux Tribe Yates, N.D. (also in S.D.)	7/1/89
5	Three Affiliated Tribes New Town, N.D.	7/1/89
3	Turtle Mountain Band of Chippewa Belcourt, N.D.	7/1/89
11	Rosebud Sioux Tribe Rosebud, S.D.	7/1/89
10	Oglala Sioux Tribe Pine Ridge, S.D.	7/1/89
6	Sisseton-Wahpeton Sioux Tribe Agency Village, S.D.	10/1/89
9	Lower Brule Sioux Tribe Lower Brule, S.D.	10/1/89
8	Cheyenne River Siour Eagle Butte, S.D.	10/1/89
16	Shoshone and Arapahoe Tribes Ft. Washakie, Wy.	7/1/89
21	Ft. Peck Assiniboine and Sioux Tribes Poplar, Mt.	7/1/89
20	Shoshone-Bannock Tribes, Inc. Ft. Hell, Id.	10/1/89
19	Lummi Indian Tribe Bellingham, Wa.	10/1/89
18	Makah Indian Tribal Council Meah Bay, Wa.	10/1/89
17	Stillaquamish Tribe Arlington, Wa.	10/1/89
Consortium	N. W. Tribal Board Sedroi Woolley, Wa. (Noosack and Upper Skagit)	10/1/89
23	Red Lake Tribal Council Red Lake, Minnesota	01/01/90
24	Eastern Band of Cherokee North Carolina	01/01/90
25	Mescalero Sioux New Mexico	01/01/90
26	Tohona O'Odham (Papago) Arizona	01/01/90
27	Hualapai Arizona	01/01/90

Alaska Native Organizations
JOBS programs

Name of Organization	Date of Implementation
Cook Inlet Tribal Council, Inc. Anchorage, Ak.	7/1/89
Tanana Chiefs Conference, Inc. Fairbanks, Ak.	7/1/89
Central Council Tlingit and Haida Indian Tribes of Alaska Juneau, Ak.	7/1/89
Association of Village Council Presidents Bethel, Ak.	7/1/89
Kodiak Area Native Association Kodiak, Ak.	7/1/89
Aleutian-Pribiloff Islands Anchorage, Ak.	7/1/89
Bristol Bay Native Association Dillingham, Ak.	10/1/89
Kawerak, Inc. Nome, Ak.	10/1/89

JOBS PROGRAM

Educational activities are a required component of the jOBS program. All State programs must offer high school or equivalent (combined with training as needed), basic and remedial education to achieve basis literacy, and education for persons with limited English proficiency.

Question. How are the States going to provide AFDC recipients with these [mandatory JOBS program educational] activities?

Answer. States will use existing resources and may directly offer or contract for other mandatory educational services. (Under regulatory requirements regarding maintenance of effort, State JOBS programs may make contracts and arrangements for services only to the extent that they are not otherwise available on a non-reimbursable basis.)

Question. Will States use high schools, community colleges, or proprietary schools?

Answer. States may use all of these kinds of institutions, as well as other resources, such as those offered by the voluntary adult literacy community, public area vocational-technical schools, and alternative high schools.

Question. Will States rely on the Jobs Training Partnership Act to provide some schooling?

Answer. Since the JOBS program is required to be coordinated with other relevant education and training programs, we expect that States will execute agreements with JTPA programs for their services.

Question. Will States require young parents to go back to the same high schools they dropped out of?

Answer. The program regulations take into account the sense of the conference report (H.R. Rep. No. 998, 100th Congress, 2nd Sess. 142 (1988)), which states that, where enrollment in regular high school programs is deemed inappropriate, the State agency that is responsible for JOBS is expected to identify or develop alternative educational activities to meet the needs of JOBS participants.

Through the process of assessment and employability planning, the State will determine what activities should appropriately fulfill the needs of each participant. Thus a non-traditional alternative high school or General Education Diploma (GED) program may be selected for the participant. However, the State could place the participant in his/her former school if there are JOBS program resources that address the problems which led to the drop out and that provide child care and other JOBS supportive services.

Further, under the JOBS program, a participant who is under age 18 but beyond the compulsory school attendance rules of the State may be excused from high school or high school equivalency activities. The excuse may be made if the approved State JOBS plan contains criteria that provide for placement in other educational activities or skills training combined with education. Provisions relating to the educational participation requirements for older teen participants and those 20 and above who do not have high school or equivalent credentials similarly allow for alternative educational or work activities when the State determines those activities to be appropriate for fulfilling the participant's employability plan.

Question. Final regulations on the JOBS program define basic literacy as at least completing grade 8.9. How many States have defined basic literacy at a higher level?

Answer. Twenty-five of the 27 States that have implemented JOBS submitted their State plans before the regulations became effective and so were not required to provide information as to how they chose to define a basic literacy level relative to the program. Neither of the two States that implemented JOBS following adoption of the JOBS regulations indicated that they chose to raise their definition of basic literacy for JOBS above the floor specified in the regulations.

CHILD CARE UNDER THE JOBS PROGRAM

The Family Support Act requires States to guarantee child care to the extent that such care is determined by the State agency to be necessary for an individual's participation in the JOBS program. States may provide child care directly or through contracts, vouchers, reimbursement, or cash.

Question. What methods of child care are most States planning to use?

Answer. Of those States which have implemented JOBS to date, most are offering a mix of methods as suggested in the statute - e.g, providing the care directly, use of contracts or vouchers, advance payment of cash or vouchers to caretaker relative, reimbursement of caretaker relative, arrangement for non-reimbursed care, child care disregard, and other arrangements deemed appropriate by the State.

Question. Which States plan to provide child care directly?

Answer. A number of States are considering this option; they have until April 15, 1990 to advise us of their final decisions in this area.

Question. Does the $163 million appropriated for child care under the JOBS program in FY 1990 assume primarily center-based child care (if not, what does it assume)?

Answer. The Work Program child care estimates have been revised upward for FY 1990 to $206 million to reflect new assumptions about participation in JOBS and new information from State plans concerning child care unit costs. The estimates assume that about a quarter of families will use center care facilities, while the remainder are assumed to use family day care, relative care, and some form of after school care. Estimates about the distribution of types of care used as well as proportions paying for care are based largely upon data from the Survey of Income and Program Participation (SIPP) and MDRC GAIN study reports.

Question. If some States provide child care directly, would the costs associated with obtaining liability insurance and the like be reimbursed at the 50 percent Federal matching rate (as with administrative costs) or at the higher matching rate for child care services?

Answer. Administrative costs (such as liability insurance) incurred by the State agency in providing direct child care services will not be treated like regular AFDC or child care administrative costs, but as program expenditures. They will therefore be matched at the FMAP rate and will be subject to the local market rate and statewide limits for child care benefits. The costs of agency-provided care will thus be treated like costs of other providers.

Question. What impact will the JOBS child care provision and the transitional child care provision have on existing day care arrangements?

Answer. We do not know the exact impact of the child care provisions on existing day care arrangements. However, earlier welfare work programs did not create the child care demand that some States expected.

Question. Final regulations for the JOBS program limit the guarantee of child care to families with dependent children under age 13 (with exceptions, e.g., those with physical or mental handicaps). How can you reconcile this age cutoff with the need for supervision to protect many young teenagers from dangers and temptations?

Answer. We limited the guarantee to children under age 13 for several reasons. A number of recently enacted laws, including the tax credit for child care, use age 13 as their limit, so we wished to be in conformance with these other programs. It is a sensible limit, since most parents no longer seek child care for children in their teens; indeed, many teenagers earn money acting as care providers for younger children. In addition to the exceptions already identified, the regulations provide for child care to be continued for children found in need of it due to being under court supervision.

CHILD SUPPORT ENFORCEMENT PATERNITY ESTABLISHMENT

The Family Support Act requires States to annually determine paternities of a specified share of child who receive AFDC or child support enforcement services. A State is to receive reduced federal matching funds unless its paternity establishment percentage for a fiscal year is (1) 50 percent or greater, (2) equal to or greater than the national average, or (3) equal to what it was in FY 1988, increased by 3 percentage points from FY 1988 to FY 1991 and by 3 percentage points each year thereafter.

Question. Do you think that States will be able to meet these new performance standards?

Answer. Our assessment is that the majority of States are already at the standard or near enough to it to be able with modest effort to meet the standard. Some States, however, will have to greatly change their present mode of operation to meet the standards. For this reason, the requirements phase in over several years. A few may not be able to do so by FY 1991.

Question. Why have States had such a bad record in establishing paternities?

Answer. Nationally, the program established over 330,000 paternities in FY 1989, an increase of more than 43 percent from the number established in FY 1985.

There are, however, several possible reasons for some States' mediocre performance in the area of paternity establishment. Some Administrators take a strictly short-run perspective and believe that it is not worthwhile to establish paternity if the father cannot pay immediately. The more appropriate perspective reasons that most fathers do get fulltime jobs and that paternity is a present investment in a future gain.

In fact, the sentiment that paternity establishment is a high cost, low payoff activity--even though it has been contradicted by OCSE-sponsored research--has been a major hurdle to overcome. Moreover, some states have cumbersome and difficult court procedures for establishment of paternity and with the best intentions the State simply has a hard time getting the job done.

JOBS PROGRAM FOR NONCUSTODIAL PARENTS

The Family Support Act of 1988 (P.L. 100-485) authorizes the Secretary to permit up to five States to provide services under the JOBS program, on a voluntary or mandatory basis, to noncustodial parents (generally, fathers) who are unemployed and unable to meet their child support obligations.

Question. Has any State applied to the Secretary for permission to extend the JOBS program to non-custodial parents unable to make their child support payments? If so, what State or States? If not, what do you think is the reason?

Answer. No State has applied because the demonstrations have not been announced. We expect to solicit demonstrations soon. Discussions with DOL and several foundations interested in participating are underway, in advance of formulating our announcement of grant availability.

INTERSTATE COMMISSION

The Family Support Act of 1988 (P.L. 100-485) established a Commission on interstate child support. the purpose of the Commission is to submit to Congress recommendations to improve the interstate establishment and enforcement of child support awards and to revise the Uniform Reciprocal Enforcement of Support Act. The law says that the members of the Commission shall be appointed by July 1, 1989.

Question. Why has the Administration not yet (as of January 9, 1990) appointed its seven members to this Commission so that it can start work on studying interstate enforcement of child support orders, which is considered by most administrators, observers, and affected parties to be one of the more intractable problems of the Child Support Enforcement program?

Answer. We expect the announcement of Secretarial appointments in the near future.

Question. Will the Commission receive the full $2 million authorized by the Family Support Act?

Answer. In the FY 1990 appropriation, the Congress identified $1 million to be used to pay for the Commission. Specific new funds for the Commission in FY 1991 have not been requested. As appropriate, this issue will be addressed in the context of available funds in the Program Administration appropriation.

JOBS PROGRAM

The Manpower Demonstration Research Corporation (MDRC) (a nonprofit organization based in New York City that has conducted a number of studies on State AFDC work and training programs) has a contract with the Department of Health and Human Services to examine the JOBS program in several States.

Question. What does the contract [to examine the JOBS program] specify that MDRC do?

Answer. MDRC will conduct an evaluation of selected JOBS programs under section 1115 of the Social Security Act. The evaluation will be based on the JOBS evaluation description in the Family Support Act and will consist primarily of these components:

1. Impact analysis: To assess the net impact of JOBS at selected sites by analyzing key outcome measures, including labor market outcomes, levels of receipt of AFDC and other benefits, family income and poverty status, receipt of employment-related services, and educational attainment. In addition to evaluating the overall impact of JOBS programs, in some sites we plan to assess the incremental impact of different JOBS program models.

2. Process analysis: To examine the context for implementation of JOBS (e.g. labor market, caseload demographics, etc.), the programs and services put into place (including systems for case management), and participation levels in different JOBS components and the factors that affect participation.

3. Cost effectiveness analysis: Program costs will be compared to benefits from the perspective of the welfare participant, government budgets, and society as a whole.

4. Effects on children: Child Trends Inc., a subcontractor with extensive experience in the area, will be assessing the effect of the mothers' participation in JOBS on children.

The HHS contract with MDRC also specifies such related tasks as, for example: preparing a synthesis of past research findings on the effects on AFDC recipients of employment and training programs, assisting HHS in reviewing potential evaluation sites, providing technical assistance on data collection to local AFDC staff at evaluation sites, and providing support at meetings of the Federal Advisory Panel prescribed in the Family Support Act.

Question. What questions will the MDRC evaluators seek to answer?

Answer. The key questions to be addressed in the above analyses include the following:

1. What strategies - such as program components and sequencing strategies - work best in helping welfare recipients to increase employment and reduce dependency? Are those strategies cost-effective?

2. How effective are remediation and other basic education services for adult recipients? How feasible and effective are employment programs that emphasize "human capital development" approaches - particularly the provision of basic education and skills training - as compared with more direct labor force entry approaches like job search and work experience?

3. What program approaches work best for what types of AFDC recipients?

4. How effective is the requirement that young AFDC parents remain in high school until they graduate?

5. Is it feasible and cost-effective to require women with young children to participate in education, employment, and training programs, if child care services are guaranteed?

6. What participation rates are achieved under JOBS?

7. How should JOBS performance standards be designed?

8. Does the mother's participation in JOBS programs have an effect on her children.?

FRAUD PREVENTION

As you know, the Family Support Act of 1988 (P.L> 100-485) requires State to provide appropriate measures to detect fraudulent AFDC applications before the family's eligibility is established. In addition, the Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203) authorizes Federal matching funds for fraud control programs established by States. The preeligibility fraud detection program receives 50 percent Federal matching funds, but the AFDC fraud control program receives 75 percent Federal matching funds.

Question. How does the Federal Government monitor Federal reimbursement for the AFDC preeligibility fraud detection program and the AFDC fraud control program?

Answer. Federal reimbursement for the AFDC preeligibility fraud detection and optional fraud control programs is monitored by the FSA Regional Offices. Upon receipt of the State's Quarterly Statement of Expenditures, the FSA Regional Office's financial management staff will evaluate the claim and may conduct an onsite review to determine the allowability of the costs.

Question. How many States are operating an AFDC fraud control program? Have these programs been effective?

Answer. As of this date, a total of 17 States are operating the optional AFDC fraud control program. Since States cannot implement the full AFDC disqualification hearing procedures until final rules are published, it is premature to evaluate the effectiveness of these programs.

Question. How much has the Federal Government and the States spent on them?

Answer. In FY 1989, combined Federal and State spending on the AFDC fraud control program totaled $11.3 million.

Question. Is there a penalty--beyond rejection of application--for being found guilty under the preeligibility fraud detection program?

Answer. The penalty imposed on an individual who is found to have committed an intentional program violation at application through the preeligibility detection process is dependent upon: (1) whether or not the State agency has selected the option to operate an optional fraud control program in accordance with section 416 of the Social Security Act; and (2) current State law governing AFDC program violations.

State agencies that are exercising the optional AFDC fraud control program are required to proceed against any individual who it believes has committed an intentional program violation. If such an individual is determined to have committed an intentional program violation, he/she is disqualified for six months for the first offence, 12 months for the second offence, and permanently for the third offence. This means, for example, that an applicant who commits his/her first program violation cannot reapply for a period of six months. The State also has the option to seek a further penalty in court if allowed under its laws.

State agencies who do not choose to implement the optional AFDC fraud control program can only rely on penalties that are permitted under State law. In States whose laws fail to provide a penalty for filing a fraudulent application, the only penalty may well be the denial of the application.

Question. Has the program been effective?

Answer. Our interim final rules at 45 CFR 235.111 require States to perform an annual evaluation of their preeligibility fraud detection programs. Because we have not received all of the annual evaluations at this time, it would be premature to indicate the effectiveness of this program. We believe, however, that preeligibility fraud detection measures are an essential screening device which enables State agency staff to improve the accuracy of initial eligibility and payment determinations.

SUPPLEMENTAL SECURITY INCOME

Question. What percentage of SSI recipients are homeless (i.e., do not have a permanent address)?
Answer. Data are not available for estimating the number of homeless cases.

Question. Have recent efforts of SSA staff (and others) to explain the SSI program to persons living in shelters been successful in helping eligible homeless persons obtain SSI benefits?

Answer. We believe that SSA staff efforts have successfully helped many potentially SSI-eligible persons living in shelters to obtain program benefits. These efforts include explaining program benefits and requirements to homeless people and the people who provide them with services. They also include arrangements tailored to local conditions that facilitate the application process for homeless people and ensure that they continue to receive benefits for as long as they are eligible.

Question. Does the Administration agree with the view that the Listing of Impairments for children should be revised?

Answer. The Administration agrees that there is a need to review the childhood disability listings (Part B of the Listing of Impairments). SSA is initiating an across-the-board review of the Part B listings to identify the nature and extent of the needed revisions. The review is designed to ensure that the revised listings (1) clearly, adequately, and appropriately identify criteria, by impairment, to establish disability in childhood; (2) are consistent in the level of severity of impairment identified; (3) adequately take into account the specific effects of impairment on growth and development; and (4) properly supplement the Part A (adult) listings to ensure consistency of adjudication.

SSA is currently identifying appropriate specialists, to include specialists in medicine, with a concentration in pediatric medicine, and psychology, education and rehabilitation, to participate in the across-the-board review.

Question. The Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) establishes a permanent SSI outreach program for blind and disabled children. By what percentage is this program estimated to increase the SSI caseload?

Answer. The permanent SSI outreach program for blind and disabled children is expected to increase the SSI caseload by less than 1 percent in FY 1991.

Question. Has the rise in the number of cocaine-addicted babies increased the SSI rolls?

Answer. There is no way to tell if there has been an increase in the SSI rolls due to the rise in the number of cocaine-addicted babies. The diagnostic code for cocaine addiction or substance abuse is new and we have not seen cases with these codes on our sample files. Data for the last few years show a slight increase in the number of children under the age of one year, but the increase does not have a significant impact on the overall caseload.

Question. Do cocaine addicted babies generally manifest such relatively severe disabilities that they should be presumed to be disabled for SSI purposes?

Answer. Cocaine addicted babies vary greatly in the symptoms they exhibit, depending on the degree of exposure to the drug, length of time following withdrawal from exposure to the drug, and the efficacy of any specific treatment. Many of these exposed babies exhibit considerable restlessness and irritability following birth, with these symptoms often clearing up in a few days to weeks following withdrawal. At times the period of restlessness and irritability is followed by a period of diminished responsiveness. The course of the symptoms cannot be predicted and partial or complete recovery occurs sufficiently often that a presumption of disability is not indicated.

PROGRAM ADMINISTRATION

The Family Support Administration (FSA) was established administratively as an operating division of the Department of Health and Human Services effective April 1, 1986. The Department of Health and Human Services said that the purpose of the new agency was to consolidate Federal resources that aid low-income families and refugees and promote community development. The Administration said that combining the accounts of the Offices of Family Assistance, Child Support Enforcement, Community Services, and Refugee Resettlement would give the FSA the flexibility to place scarce resources where they are most needed.

Question. Has FSA achieved its goal?

Answer. Combining the accounts of the Offices of Family Assistance, Child Support Enforcement, Community Services and Refugee Resettlement has given the FSA the flexibility to place resources where they are most needed. By consolidating financial and administrative functions into staff offices within FSA, we gained economies of scale that have allowed us to operate effectively with fewer employees devoted to these functions. We have also been able to more effectively adjust the levels of staffing devoted to program functions on the basis of need. For example, with the creation of the Job Opportunities and Basic Skills (JOBS) training program in the Family Support Act of 1988, we needed to quickly shift staffing resources into the Office of Family Assistance. Because the program administration accounts are consolidated in FSA, we could do so very easily.

Question. In FY 1986, the appropriation for program administration was $88.4 million, as compared to $86.8 million in FY 1990. Was this decrease expected?

Answer. Comparisons of program administration appropriations for FY 1986 and FY 1990 reflect several factors at work. Excluding those administrative cost components which do not directly impact on program operations, the increase in Congressional appropriations over this period has not kept pace with the increase in wage and salary pay schedules. Nevertheless, we still have $8.8 million of the FY 1986 funds appropriated for Child Support Enforcement which we expect to obligate this year to develop an interstate network.

While the magnitude of the reduction in real FSA operating expenses has resulted in a greater than anticipated shrinkage in FSA staffing, contractual resources, travel and other expenses, it should be noted that Federal deficit considerations and budget restrictions have likewise affected other government agency operating activities.

Question. Has the reduction in staff, from 1,134 in 1986 to an estimated 1,029 in 1990 adversely affected program performance?

Answer. The reduction has not adversely affected program performance. By achieving economies of scale, increasing office automation and effectively managing the downsizing process, we have been able to successfully fulfill the mission of the agency and effectively administer all of our programs. For example, one of the major indicators of the effectiveness of the Child Support Enforcement Program is the total annual collections reported by the States. Record levels of collections have been achieved in each year since the creation of FSA.

AMERICAN SAMOA

The Family Support Act of 1988 (P.L. 100-485) authorized American Samoa to participate in all programs under title IV of the Social Security Act. Its funding is limited to $1 million per year for AFDC, foster care and adoption assistance.

Question. Is American Samoa currently operating an AFDC program? If not, when do you expect American Samoa to begin its program? If so, when did the program start?

Answer. On January 10, 1990, American Samoa notified the Family Support Administration that it does not wish to pursue an AFDC program at the present time, but would like to hold its future options open should conditions change. The reasons offered for this decision included the possible damaging effect of AFDC on the territory's subsistence economy and to the traditional extended family unit, as well as financial and administrative problems.

Question. What are the basic terms of the American Samoa program: need and payment standards, income and resource limits?

Answer. American Samoa has chosen not to implement a program at this time.

UNEMPLOYED PARENT PROGRAM

Under previous law, States had the option of offering AFDC to children in two-parent families who were needy because of the unemployment of the principal earner. The Family Support Act requires all jurisdictions without this program as of September 26, 1988, to make it

available, for at least 6 months (out of 12 months), to needy two-parent families in which the principal earner is unemployed, starting on October 1, 1990.

Question. What effect will [the required implementation of an unemployed parent program] have on State budgets?

Answer. This new provision will increase State budgets in those States which did not previously operate an AFDC-UP program. However, these States will have some control over the extent of the program's impact on their budgets, since they may elect a time limitation for cash assistance under which the State may deny such assistance if the family received AFDC-UP cash assistance in six of the preceding 12 months. It is difficult to determine the full extent of how these individual State budgets will be affected because of the flexibility provided States under the new UP provision.

Question. How many States are likely to provide the new AFDC-UP benefit for more than the 6 months under the new law?

Answer. Since this requirement is not effective until October 1, 1990, we do not have information on the number of States that might go beyond the minimum program.

Question. What are the administrative implications of providing AFDC-UP benefits for only 6 months of every 12-month period?

Answer. Although the AFDC-UP benefits are time-limited, there will be certain administrative tracking needs in order to monitor the clients' periodic eligibility for those benefits, as well as for other benefits such as Medicaid, education, training, and employment services that will continue in the interim between the limited periods of AFDC-UP benefits.

Notification requirements will also need to be met to keep the family informed concerning both eligibility and termination of eligibility for benefits, including when such benefits could be reinstated. The family also must be informed of the education, training, and employment services activities, including JOBS program activities, for which it is eligible.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Question. To what extent have private sector initiatives and energy providers contributed to easing home energy costs burdens recently?

Answer. The most recent source of data on such initiatives is from the 1988 National Fuel Survey undertaken by the National Fuel Funds Network, Edison Electric Institute, and the American Gas Association.

The survey includes data from 121 private fuel funds that received utility customer and company donations. The report indicates that a total of $31 million was distributed to 193,000 households in 1987 by the 121 private fuel funds. The average benefit was $161.

Question. Are prohibitions against home energy shutoffs in crises increasing among the States?

Answer. The most recent source of data is the Survey of Electric and Natural Gas Utility Uncollectible Accounts and Service Disconnections for 1984. The National Association of Regulatory Utility Commissioners (NARUC) surveyed state public utility commissions (PUCs) and published the results in October 1985.

The NARUC survey does not include data on state legislation prohibiting cold weather shutoffs. However, the NARUC survey includes data on state PUC rules prohibiting cold weather shutoffs. Of the 47 state PUCs responding to the survey, 38 PUCs (81%) restricted regulated utilities in implementing residential service disconnections during the winter months.

According to the survey results, the 47 PUCs based their winter restrictions on shutoffs on one or more of the following criteria:

- 6 PUCs included an outright seasonal ban or moratoria on winter shutoffs.
- 13 PUCs based winter restrictions on temperature criteria.
- 13 PUCs based winter restrictions on inability to pay.
- 13 PUCs based winter restrictions on the presence of elderly or handicapped persons in the household.
- 11 PUCs based winter restrictions on household eligibility for the LIHEAP.
- 10 PUCs based winter restrictions on various other criteria.

Question. How much assistance is contributed by private consumers through "check offs" on their utility bills and similar plans?

Answer. The most recent source of data on private contributions is from the 1988 National Fuel Survey undertaken by the National Fuel Funds Network, Edison Electric Institute, and the American Gas Association. The survey includes data from 121 private fuel funds that received utility customer and company donations. The report indicates that a total of $31 million was distributed to 193,000 households in 1987 by the 121 private fuel funds. The average benefit was $161.

Question. Section 505 the 1988 Family Security Act authorized a three year job creation demonstration which will use community development corporations to promote job opportunities for those on public assistance. The Fiscal Year 1990 budget year appropriation bill provided some $10 million for Family Support Administration research and evaluations. The conference report accompanying the bill identified the job creation demonstration as one of the activities to be funded. A number of members of the Senate, including myself, have written to the Secretary urging that this demonstration be fully implemented.

Please provide the Committee with a complete status report on the demonstration. Including its placement within FSA, the amount of funds that will be allocated to it, the number of grants to be made and the schedule for implementation.

Answer. A Program Announcement announcing the availability of funds and requesting applications has been developed and is currently being cleared in the Family Support Administration. The program will be administered by the Office of Community Services. Approximately $3.5 million will be available for making grants to 5-10 private non-profit organizations. Grants will be made in the fourth quarter of FY 90.

Question. It is my understanding that the Community Economic Development program funded out of the CSBG discretionary fund is the only federal program which targets economic development efforts by community development corporations working in poor communities. What is the rationale for terminating this program in FY 91?

Answer. Since funds are available for similar services under other Federal funding authorities, e.g. the Small Business Administration and the Minority Business Development Agency in the Department of Commerce, the Department is not supporting reauthorization.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

OFFICE OF REFUGEE RESETTLEMENT

Question. Ms. Thomas, for the past two years, Congress has had to provide funding to meet the program shortfalls in the previous fiscal year for the Voluntary Agency Matching Grant Program. Do you anticipate a shortfall in the program for fiscal year 1990? How many refugees were resettled under the program in FY 89, and how many do you project will be resettled in FY 90 and FY 91?

Answer. We do not anticipate a shortfall in the Voluntary Agency Matching Grant Program in FY 1990. In

FY 1989, $15,808,000 was available for this program, accounting for the resettlement of approximately 16,500 refugees. For FY 1990, $40,000,000 was appropriated as part of the HHS Appropriations Act, and the same amount is requested for FY 1991. An appropriation of $40,000,000 is sufficient to cover the resettlement of about 41,800 refugees.

In FY 1989, a number of refugees were resettled by the Council of Jewish Federations in accordance with matching grant program procedures even though sufficient funds were not available for the Federal match. In recognition of this, Congress included $14,936,000 in the FY 1990 Foreign Operations Appropriations Act to help cover such FY 1989 costs.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Question. Ms. Thomas, how many households received heating assistance in fiscal year 1989? How does this compare to fiscal years 86-88?

Answer. In fiscal year 1989, about 5.6 million households received LIHEAP heating assistance, compared to 5.8 million households in FY 1988, 6.5 million in FY 1987, and 6.4 million in FY 1986. We estimate that an unduplicated total of 5.9 million households received LIHEAP heating assistance and/or winter crisis assistance (assistance with heating costs) in FY 1989, compared to 6.2 million households in FY 1988, 6.8 million in FY 1987, and 6.7 million in FY 1986.

Question. How much did the states receive in oil overcharge funds in FY 89 and how much does the Department estimate will be released to the states in FY 90 and FY 91?

Answer. The states received $3.3 billion in oil overcharge funds between FY 1986 and FY 1989. They received about $230 million of this total in FY 1989. According to Department of Energy estimates, the states should receive about $350 million in additional oil overcharge funds in FY 1990 and about $100 million in FY 1991.

Question. Does the Department project stable energy prices for FY 91? How does the cost of heating fuels in FY 90 compare to the cost in FY 91?

Answer. We obtain energy price projections from the Department of Energy. The Department of Energy advises us that it anticipates relatively stable home energy prices for FY 1991. Such projections assume normal temperatures throughout the country.

OFFICE OF HUMAN DEVELOPMENT SERVICES

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

SUPPORT FOR AGING PROGRAMS

Question. The FY 1991 budget request for aging programs is $749 million, an increase of $1 million to support the White House Conference on Aging. There are no increases for nutrition and supportive services -- no increases for aging research -- and no increases for frail in-home elderly services. THIS BUDGET REPRESENTS A CUT IN FEDERAL SUPPORT FOR AGING PROGRAMS. In view of the fact that the age 65 and over population is the fastest growing age group in the country, and the fact that the Administration on Aging is supposed to be the focal point and advocate for aging programs, I can only conclude one of two things from this budget -- 1) We are doing everything that needs to be done; or 2) Aging programs are not receiving the priority that Congress intended when it established the Administration on Aging.

Why are there no increases in this budget for aging programs?

Answer. In the past, services levels have increased each year, even if no increase in funding occurred. This trend is expected to continue, and therefore no increase is requested.The Administration on Aging expects contributions by service recipients to continue to increase, thus providing additional resources to support the provision of services. The continuing emphasis which AoA and the State and area agencies have placed on enhanced program efficiencies will also produce additional resources available for expanded services.

Question. Did the Administration on Aging request increases in its original budget submission for aging programs or propose any new initiatives?

Answer. In preliminary stages of the budget process, increases for Aging programs were considered and discussed. However, we are confident that services to the elderly will continue to increase and improve within requested funding levels.

FOSTER CARE

Question. I continue to be concerned over the tremendous increases in foster care administrative costs. During the almost 10 years since the Congress responded to the need for a Federal presence in helping the States to meet their responsibilities in providing care to AFDC children in the foster care system, administrative costs have soared, increasing by 2,800 percent. No one can argue that these are not tremendous increases. This compares to a 99 percent increase in the number of children served and 233 percent increase in maintenance payments. You will note from the "pie" chart, that in FY 1982 administrative and training costs accounted for only 19% of the pie. By FY 1991, administrative costs will account for 51% of the pie. In fact in FY 1991 administrative costs will exceed maintenance payments for the first time. Is there any evidence that we are getting improved or increased services as a result of these tremendous increases in administrative costs?

Answer. We do not have any evidence that increased administrative funds are being used to improve or increase services.

ADMINISTRATIVE COSTS

Question. Your budget proposes to cap increases in foster care administrative costs at 10%. This is similar to the approach I proposed last year, which would have limited increases to three times the cost of living increase. Because the authorizing statute is so broad, are States shifting the costs to this opened-ended entitlement program, and thus freeing up State monies for other projects?

Answer. Although we know that cost-shifting has occurred in some States, we do not have sufficient data to draw the conclusion that cost-shifting is occurring on a national scale.

REFUTE ARGUMENTS AGAINST CAP

Question. Arguments against capping administrative costs are varied -- the most frequently heard are that child protective and case management services would be reduced and that there is not sufficient information on which to base a cap on administrative expenses. What is your response to those arguments?

Answer. The proposed cap allows for an increase of ten percent each year, well in excess of the inflation rate. Therefore, services may still be expanded under the proposal. Further, title IV-E should not be the source of child protective services funding. State programs and services programs such as Child Welfare Services (Title IV-B) and the Social Services Block Grant (Title XX) are appropriate revenue sources for those services.

CAPPING ADMINISTRATIVE COSTS IS FAIR

Question. The authorizing legislation has a caveat that would limit foster care administrative costs once funding for child welfare services under Title IV-B of the Act reaches $325 million. By increasing appropriations for child welfare services by $113 million, we could save over $570 million in foster care administrative costs. Yet, should the appropriations "trigger" this cap on administrative costs, 44 States would receive less than they received in FY 1989 and 29 of those States would lose 50% or more of what they are currently receiving in Federal reimbursements for administrative costs. Now this approach does seem arbitrary and would appear to cause unreasonable harm. How would your proposal to control administrative costs differ from the approach in current law?

Answer. The current law provision you have described is a ceiling on all costs. There is no separate provision on the amount of allowable administrative costs for which a State may be reimbursed if the current law ceiling is "triggered". If "triggering" were to occur, States would have to decide on the distribution of their claims between administration and payments.

Under our proposal, a general ceiling would not be enforced and maintenance payments and training would continue to be open-ended entitlements. We are proposing to limit increases in administrative costs, on a State by State basis, to no more than ten percent a year without impacting on other parts of the Title IV-E program.

MONITORING/AUDITING OF FOSTER CARE

Question. In view of the fact that these administrative costs continue to rise, how many reviews, audits and/or site visits do you have budgeted for FY 1991?

Answer. We expect to be able to perform on-site reviews in at least 25 States during fiscal year 1991.

SSI OUTREACH

Question. In FY 1990, Congress approved a $3.5 million appropriation for improved outreach to potential recipients of Supplemental Security Income as part of the Social Security Administration funding. How is the program being coordinated with State and area agencies funded under the Older Americans Act?

Answer. The Administration on Aging (AoA) is committed to Supplemental Security Income (SSI) Outreach. In November, AoA signed a Memorandum of Understanding (MOU) with the Social Security Administration (SSA) and the Health Care Financing Administration (HCFA). The purpose of the MOU is to allow these three agencies to work collaboratively to respond to the need for increased coordination among programs impacting on the elderly. Special efforts will be made to increase participation in programs of AoA, SSA, and HCFA through special outreach efforts which focus on "hard to reach" individuals such as low-income minorities, non-English speaking and rural older persons, the homeless, and others.

The Administration on Aging has worked to ensure its aging network is aware of the Social Security Administration's SSI Outreach efforts. The Administration on Aging encouraged SSA to mail a copy of their Notice of Intent Announcement published in the Federal Register to all State and Area Agencies on Aging. The Administration on Aging notified the ten regional offices of the Notice of Intent and encouraged them to alert the States. State and Area Agencies on Aging will be encouraged to submit applications when the formal announcement is made by SSA.

OMBUDSMAN

Question. The General Accounting Office recently published a report that found the role of the Title III long-term ombudsman program in board and care facilities to be rather minimal. Given that the potential for abuse of elderly and disabled residents in such facilities is great, what recommendations do you have to improve ombudsman oversight in such facilities.

Answer. The responsibility to investigate complaints regarding board and care facilities was added to the Ombudsman Program by the 1981 Amendments to the Older Americans Act. The ombudsman programs have added board and care coverage incrementally. Some state and local board and care ombudsman programs are more developed than others.

Ombudsman oversight can be improved through increased training, sharing of best practice among the States and other forms of technical assistance, utilization of volunteers and addition of staff, where local and State ombudsman budgets permit.

The Administration on Aging is funding technical assistance to the States through a cooperative agreement with the National Association of State Units on Aging, with a sub-contract to the National Citizens Coalition for Nursing Home Reform, to operate the National Center for Long Term Care Ombudsman Resources. Through National and State training sessions and telephone conference calls, the Center enables the States to share best practice and develop improved strategies and skills for ombudsman work in the board and care area.

Two recent initiatives of the American Association of Retired Persons (AARP) illustrate improved strategies for recruitment and utilization of volunteers in the board and care area. One of these is a highly successful effort by AARP's Legal Counsel for the Elderly to recruit volunteers for selected ombudsman programs by mailing a recruitment letter to AARP members in selected area codes. The other is a joint project between AARP and the Anne Arundel County Maryland local ombudsman to place volunteers in board and care homes, sheltered housing, and foster care homes. Through this project, called ALFE (Assisted Living Facilities for the Elderely), twenty-one ombudsman volunteers currently spend two to three hours in their assigned facilities, thus reducing the isolation of both residents and home operators. The Administration on Aging has recently publicized both of these model initiatives throughout the network on aging.

Question. What conclusions have you drawn from the congressionally mandated study on the role of the Ombudsman Program in board and care facilities conducted by AoA?

Answer. The report is currently in clearance within the Department.

NEED FOR AGING PROGRAMS

Question. We are experiencing a rapid growth in this country in the number of frail elderly persons who need special assistance to avoid institutionalization. I am particularly sensitive to this problem since my home State of Iowa has the highest percentage of population over age 85 in the Nation. As the Administration on Aging appears to be the focal point for promoting and outlining strategies to carry us into the 21st Century, what are you doing to develop programs that will avert a crisis when the overage 65 population explodes?

Answer. We are keenly aware that the segment of the aging population which is very old is growing at a greatly accelerated rate.

We believe that it is altogether fitting and appropriate that, as we approach the last decade of the 1990's and the Silver Anniversary of the Older Americans Act, we begin to expand efforts and prepare our society to address policy issues which will carry through the 1990's and into the 21st Century. It is important that our society becomes focused on the need to build adequate capacity to respond to the dramatic increases in the older population during the next century. This is the major focus and thrust of the AoA goals which were published in September, 1989.

After an extensive developmental process which was grounded in dialogue with advocacy and interest groups in the field of aging including State Directors on Aging, Area Agency Directors, service providers, the academic community, the Federal Council on the Aging, representatives of the Leadership Council of Aging Organizations, and with members of Congressional committees relating to aging, we published goals in eight areas of major activity. Those goals are:

<ins>Goal 1</ins> <ins>Public/Private Partnerships</ins> - Increase awareness within both the public and private sectors of the challenge of the changing demographics, and stimulate the expansion of services and resources for older persons by promoting public/private sector partnerships.

<ins>Goal 2</ins> <ins>Older Persons as a Resource</ins> - Promote the recognition of older persons as a resource to themselves, to their community, and to the nation.

<ins>Goal 3</ins> <ins>Strengthening the Family and Generational Bonding</ins> Increase understanding of the societal implications of aging, with particular attention to the development and implementation of strategies for strengthening the family and the interdependence of generations.

Goal 4 Prevention and Alternatives to Institutional Care - Promote the recognition of the importance and the development of preventive, in-home and community-based supportive services as vital components of the continuum of care.

Goal 5 Promotion and Enhancement of Effective Community based Service Systems - Promote and support the continued strengthening of comprehensive and coordinated community service systems to insure that such services are available, accessible, and acceptable to older persons.

Goal 6 Targetting - Strategic Resource Allocation - Develop and implement new strategies for more effectively targetting resources and programs on the needs of the most vulnerable older persons, with special emphasis on low-income minority elderly.

Goal 7 Manpower Development - Increase awareness of, and promote action to relieve, the critical manpower needs in the field of aging, with particular attention to the need for an adequate supply of trained personnel to care for older persons at home, in the community and in nursing homes.

Goal 8 Preparing for the 21st Century - Challenges and Opportunities for an Aging Society - Promote public information and technical assistance to targetted groups for better decisions which need to be made now to insure that public, voluntary and private sector organizations are responsive to the resources and needs presented by the increasing numbers of older persons during the first decades of the 21st century.

It is within this goal framework that AoA, serving as the focal point for promoting and outlining strategies to carry us into the 21st Century, will provide the leadership for developing programs intended to avert the crisis which your question addresses.

AGING AND NUTRITION

Question. The 1987 amendments to the Older Americans Act required that the Administration on Aging submit to Congress a study on the unmet need for supportive and nutrition services in September 1989. What is the status of this study?

Answer. This report was completed and signed by the Secretary on February 5, 1990.

Question. What are the primary unmet needs of older persons as revealed by the study -- for example, are there waiting lists of elderly for certain categories of services?

Answer. The report was compiled using information submitted by State Agencies on Aging. Because the States used different methodologies and reporting formats in developing their individual submissions, the report does not offer a definitive nationwide inventory of unmet needs. The report does, however, highlight areas that each State considers to be of greatest concern. Specific needs identified by the States include outreach, information, community education, in-home services, transportation, access to services, respite care, congregate and home-delivered meal services and senior centers. Some States reported a greater need for supportive services than for nutrition services.

Question. What recommendations does the Administration have as a result of the study findings?

Answer. The Secretary has directed the Administration on Aging to provide technical assistance to State and Area Agencies on Aging to achieve administrative improvements in the delivery of services within each State. Each State and Area Agency on Aging will be encouraged to: 1) review the manner in which Title III funds, and other resources available to the State and Area Agencies on Aging, are targetted toward the areas of unmet needs which have been identified in the State; 2) promote program efficiency to increase the units of services which can be provided with currently available resources; 3) seek to increase the level of voluntary contributions received for services in order to generate added program income that can be directed to areas of unmet needs; and 4) undertake initiatives which generate added resources for services, for example, through enhanced partnerships between the public and private sectors.

FRAIL IN-HOME SERVICES

Question. National studies indicate that in the coming decade there will be increased demand for in-home services for the frail elderly. How does your budget request for the Title III-D program for in-home services for the frail elderly reflect this concern?

Answer. The Administration on Aging recognizes that the fastest growing segment of the aging population is the very old, those 80 years of age and older, who are subject to the greater risks of impairment and disability. Funding for the Title III-D program has increased from $4,834,000 in FY 1989 to $5,756,000 in FY 1990. The budget request for FY 1991 would continue Title III-D funding at the higher level attained in FY 1990 ($5,756,000).

In addition, the Discretionary Funds Program Announcement for FY 1990, which AoA published in the Federal Register on February 9, 1990, describes a collaborative effort between the Federal domestic volunteer agency, ACTION, and the Administration on Aging to jointly support a three-year program to demonstrate innovative approaches aimed at seeking private sector support to increase the use of Senior Companions in providing in-home services to the homebound elderly. Several other Priority Areas included in the Announcement address issues which impact on the frail elderly, including a continuing emphasis on victims of Alzheimer's Disease.

AGING/TRAINING

Question. How are you using funds under the title IV training program to plan for trained personnel to provide home care services?

Answer. The Administration on Aging has funded the National Long-Term Care Resource Center, Brandeis University to address this issue by focusing on best practices for recruitment and retention of in-home worker, and developing systems for monitoring services delivery.

During Year 1 of the project, Brandeis produced Leadership Roles in Home Care Personnel Issues, and a Long Term Care Brief - Homemaker Jobs Provide Opportunities for Older Workers. Year 2 will produce an expansion of these personnel modules by conducting a national invitational conference on these issues. A third module, Cultural Diversity and the Aging Services Workforce, will be created to identify and describe successfully developed multi-cultural long term care services. Brandeis will also collect examples of successful career development programs to develop Career Ladders for Long Term Care Paraprofessional Personnel.

NUTRITION AND SUPPORTIVE SERVICES

Question. What will be the impact of the sequestration of funds in FY 1990 on the ability of State and area agencies on aging to provide nutrition and supportive services under the program?

Answer. The sequestration should have little impact on the capacity of State and area agencies to provide nutrition and supportive services.

- o The Administration on Aging expects contributions by service recipients to continue to increase, thus providing additional resources to support the provision of services

- o The continuing emphasis which AoA and the State and area agencies have placed on enhanced program efficiencies will also produce additional resources available for expanded services.

As a result, AoA expects an increase in the level of services offered in FY 1990 over 1989.

NUTRITION AND SUPPORTIVE SERVICES

Question. The number of home-delivered meals served has increased by 160 percent since 1980. Do you expect the number of home-delivered meals to continue to increase in the coming years?

Answer. Yes, considering the rapid growth in the number of frail elderly persons, we expect the number of home-delivered meals to continue to increase. In FY 1988, 8.7 million more home-delivered meals were served than in FY 1987.

Question. Should more emphasis be placed on this component of the program as compared to other services?

Answer. There is no need to place emphasis on a particular component of the Title III program since the law permits States to transfer up to 30% of the Title III allotments between Parts B and C and the Title III regulations permit up to 30% transfer between Parts C-1 and C-2 allotments. This flexibility allows States to direct their resources to address the needs in a particular area. Over the past several years, States have used this authority to increase their Supportive Services and Home-Delivered Meals allotments.

Question. What proportion of home-delivered meals providers offer meals on weekends and offer more than one meal per day?

Answer. In FY 1986, the last year in which this type of data was collected by AoA, approximately 14% of Title III C-2 providers offered meals on weekends and approximately 8% offered more than one meal per day.

Question. Do you believe that there is a need to increase the weekly and/or daily frequency of home-delivered meals.

Answer. Presently, AoA does not have documentation to support a conclusion as to the need to increase the frequency of home-delivered meals. However, we must keep in mind that Title III providers of home-delivered meals are not the only providers of home-delivered meals. Many providers are funded by public and private resources.

DATA COLLECTION

Question. The 1987 amendments to the Older Americans Act required improved data collection on recipients of supportive and nutrition services as well as expenditures on services beginning in FY 1989. What is the status of your efforts in this area?

Answer. In response to the new annual report requirements mandated by the 1987 Amendments to the Older Americans Act, AoA developed a new State Program Report form to collect annual data on programs for older persons under Title III of the Act. This report form was cleared by the Office of Management and Budget (OMB) and distributed to States. States were required to utilize the new form for the first time in reporting data for FY 1989. Currently, AoA is in the process of reviewing and analyzing the FY 1989 data submitted by State Agencies on Aging.

COST-SHARING

Question. GAO recently issued a report indicating that Congress should consider amending the Older Americans Act to authorize State and area agencies to establish mandatory charges for in-home services for the elderly. Under current law, mandatory cost-sharing is prohibited; however, voluntary contributions for services may be made. What is your position on GAO's recommendation that cost-sharing be made mandatory?

Answer. We are aware of an emerging national debate on the issue of cost-sharing for programs of the Older Americans Act. As you know, cost-sharing is being widely discussed at the present time throughout the national network of services for the aging because of the rapidly increasing need for services, the rise in the costs of providing the services and difficulty in finding funds to meet the needs. A Commissioner's Roundtable on Cost Sharing was recently convened to share the experiences and views on the issue of State and Area Agencies on Aging (AAA's), service providers, and other experts. The author of the GAO report was also present. That report was based on findings from responses to a questionnaire mailed to all State Agencies on Aging and 675 AAA's; however recipients of these services were not queried.

While the Administration on Aging and the Department do not yet have a position on this issue, it is important that the issue be viewed with an open mind. In order to better determine the willingness of participants in programs funded under Title III of the Older Americans Act to share the cost for services they receive, the HHS Office of the Inspector General has been asked to conduct a major study on this issue . By sharing experiences and different perspectives on this subject, we all will have a clearer understanding of the issues involved in cost-sharing and will be better able to evaluate the benefits and limitations of this policy.

GRANTS TO NATIVE AMERICANS

Question. Last year there was an upturn in the number of Indian tribal organizations which applied for nutrition funds (46 new tribes eligible since 1988).

Do you anticipate that more tribal organizations will apply for funds in the next funding cycle, and if so, how many?

Answer. The Administration on Aging currently funds 181 tribal organizations. However, because of the large number of Indian tribes and Alaskan villages eligible for assistance under section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b), it is not possible for AoA to predict how many new tribal organizations will be eligible to make application for FY 1990 Title VI funding. An invitation for new tribal organizations to make application for FY 1990 Title VI funding was published in the Federal Register on February 5, 1990.

RESEARCH DISSEMINATION

Question. What efforts have been made to disseminate the results of the wide range of research and demonstration initiatives supported under this program in the past?

Answer. The Administration on Aging (AoA) has traditionally relied upon its grantees to take the lead in promoting dissemination and utilization of findings and products from their research and demonstration projects. Since the mid-1970's that lead responsibility has been reinforced by an AoA requirement that potential grantees include a description of their proposed dissemination activities as part of the work plan outlined in their grant application.

For its part, AoA has taken steps to ensure that final project reports are filed with several information clearinghouses and repositories for future circulation and use. Those clearinghouses are: (1) Project SHARE, P. O. Box 2309, Rockville, MD 20852, (301) 231-9539; (2) National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, (703) 487-4600; (3) AgeLine Database, BRS Customer Services, 1200 Route 7, Latham, NY 12110, (800) 345-4277 and; (4) Acquisition Unit, Library Programs Service, U. S. Government Printing Office, North Capital and H Streets, N.W., Washington, DC 20401, (202) 275-1070

In addition, AoA has often undertaken dissemination activities with the objective of informing the Aging Network of innovative service programs which offer wide potential for replication and adaptation through reports in the Aging Magazine and Information Memoranda to the Aging Network.

For the 1990's, increased emphasis will be placed on transferring knowledge generated by the AoA sponsored research and on making practical use of the products resulting from these projects.

Question. Given the wide range of research and demonstration projects, do you believe that a portion of those monies should be specifically set aside for research dissemination activities?

Answer. The key to ensuring the dissemination and utilization of the results and products of research and demonstration (R&D) projects is to build a comprehensive dissemination strategy into the R&D program itself, a strategy that includes a dissemination component build into each of the funded projects.

As part such a comprehensive dissemination and utilization strategy, AoA is considering the following elements:

- Organize Annual Knowledge-Update seminars at a Regional or Bi-Regional level at which AoA/R&D grantees would be convened to inform Aging Network staff, service practitioners, older persons, and other appropriate audiences of their project results and findings.

- Prepare new clips for radio, T.V. announcement about R&D project reports that are of interest to the older population, i.e., "Guidebook on Housing," "Support Groups for Families with Alzheimers Patients," etc.

- Use project abstracts and related information to prepare one-page fact sheets of each R&D project. Provide fact sheets to the Government Printing Office (for inclusion in its catalog which is made available to more than 1500 depository libraries throughout the Nation) and to appropriate national organizations, directories, newsletters, and other Federal agencies whose constituencies parallel those of AoA.

- Assist AoA grantees to showcase their projects at national, regional, State, and local conferences. Ensure that all such presentations are reported quarterly to the AoA Project Officer as part of the monitoring plan.

- Seek to organize and sponsor a session on Dissemination and Utilization of R&D in Aging for inclusion in the program of the annual meeting of:

  - National Association of State Units on Aging
  - National Association of Area Agencies on Aging
  - The Gerontological Society
  - Association for Gerontology in Higher Education
  - American Society on Aging
  - The National Council on the Aging
  - Other Professional Societies

- Continue to provide Information Memoranda to the Aging Network on the many projects that are being conducted or terminated. Share copies of abstracts or executive summaries on an ongoing basis.

- Continue the AoA Interagency Agreement with the National Institute on Aging with special emphasis on collaborative support for dissemination information on Alzheimer's disease.

EXAMPLE OF ANA FUNDED PROJECTS

Question. The FY 1991 request for the Administration on Native Americans is $32 million, the same level of funding provided in FY 1990. As with the majority of programs within OHDS, there are no cost-of-living increases. Native Americans have some of the worst poverty, unemployment, health and education statistics in the country. Please provide examples for

FY's 1985 - 1989 of projects that have been funded, the dollar amounts associated with those grants and information on the current status of those projects, i. e., economic benefits, jobs created and any other objectives achieved. Examples should also include information on those projects that have not been successful with a brief explanation of the reasons for failure. For those same fiscal years provide the number of applications received, the number of applications approved and the dollar amounts associated with those applications.

Answer. The Administration for Native Americans (ANA) is a discretionary grants program which funds projects up to 36 months in duration. Projects presenting the strongest prospects for fulfilling a community's governance, social, or economic development are funded. All projects funded by ANA must be completed, self-sustaining or supported with other than ANA resources at the end of the project period. ANA does not have the staff resources to continue systematic monitoring of grants after the project period ends.
Following are examples of successful projects using ANA funds during the years 1985 to 1989:

FY 1985

Grantee: Alu Like, Inc.
Honolulu, HI

Project Title: Project to Promote Native Hawaiian Social and Economic Self-Sufficiency in Hawaii

Amount of Funding: $800,000

Benefits and Achievements:

- participated in the development of a Native Hawaiian Master Plan in the areas of vocational education, employment and training, library services, health/mental health, and housing

- assisted five local Native Hawaiian organizations to receive 501 (c)(3) status, thus making them eligible for financial support as incorporated, non-profit organizations

- undertook efforts to leverage local resources to address the needs of the Native Hawaiian community, including extensive work with the Department of Education to focus on providing basic skills to Native Hawaiians, thus enabling Native Hawaiians to more competitively secure employment

- developed increased linkages with 39 other agencies for public services and the provision of information to Native Hawaiians

- conducted outreach to 308 Native Hawaiians to identify mental health needs and services

- assisted Native Hawaiians to open or expand 47 businesses on Oahu with direct assistance to 107 Native Hawaiians in business
- assisted 18 farmers to form a bulk buying cooperative
- developed three community awareness workshops on Native Hawaiian land rights with the State Department of Hawaiian Home Lands
- developed a cooperative agreement with the Small Business Institute at the University of Hawaii to provide business assistance to Native Hawaiians
- with the State Department of Education, trained Native Hawaiian elders to work in school classrooms with teachers as resource teachers
- initiated a daily radio program, reaching an estimated 60,000 persons, on Hawaiian history, issues, services, programs, and concerns
- provided extensive services to Native Hawaiians through Alu Like's Neighbor Island centers on Hawai'i, Kaua'i, Mau'i, and Moloka'i, e.g.:
    - the conduct of a conference on Native Hawaiian rights on Kaua'i
    - the development of a computer services data bank inventory of services and providers for the Native Hawaiian community on Mau'i
    - through work with five service providers on Moloka'i, helped to establish a youth shelter for runaway and abused youth.

GRANTEE: Jamestown Klaliam Tribe

PROJECT TITLE: Three Phase Development Project

$ FUNDED: FY 1986 $99,614, - FY87 $259,993, - FY88 222,858

ECONOMIC BENEFITS & ACHIEVEMENTS RESULTING FROM PROJECT FUNDS FROM ANA.

The project, which was proposed by the Jamestown Klallam Tribe, was developed over a period of three (3) years. The projects were highly successful, and the following were accomplished:

1. A total of twelve (12) people were employed.
2. Established a tribally-chartered business development organization.
3. Purchased and manages a 38-unit apartment building and a 28-unit apartment building

4. Purchased and manages a commercial building which is fully occupied by four industrial tenants.

5. Formed SECTOR, Inc., a computer systems integration firm that specializes in multi-user equipment manufactured by Digital Equipment Corporation.

The above mention tribal projects are self-sustaining.

Fiscal Year 1986

GRANTEE: Kodiak Area Native Association (KANA) Kodiak, AK

PROJECT TITLE; Scallop Farming, Mariculture Project

$ FUNDED; $149,860

ECONOMIC BENEFITS & ACHIEVEMENTS RESULTING FROM PROJECT FUNDS FROM ANA.

Through joint venture with State of Alaska and Japanese government harvested scallops for Japan's market. Used Japanese technology experts to train local people through college level courses in the mariculture industry. In addition to scallops, blue mussels are also cultured. Received funds from USDA for research on shelflife and handline of pink scallops. Established scallop farm in one community to rear 300,000 scallops. Local market in Anchorage purchases scallops live in the shell and/or frozen. The ultimate goal is to farm one million scallops per year. Generated 10 jobs farming in one community.

Fiscal Year 1986

GRANTEE; Ute Mountain Ute Tribe, Towaoc, CO

PROJECT TITLE; WEEMINUCHE Construction Authority

$ FUNDED: $28,500 for this objective

ECONOMIC BENEFITS & ACHIEVEMENTS RESULTING FROM PROJECT FUNDS FROM ANA.

Tribally owned construction authority was established, is 8A designated and has successfully contracted and completed the following projects:

Bureau of Reclamation Brine Pipeline on the Delores River. Developed water irrigation system on 7500 acres for residential agriculture and livestock. Generated 20 jobs and Tribe profited 10% of the $1,851,000 contract.

Bureau of Reclamation Dawson Draw Road created 10 jobs and Tribe profited 10% of the $1,500,000 contract.

Cortez-Towaoc pipeline developed water systems for the community. Generated 25 jobs and Tribe profited 6% of the $3,750,000 contract.

Constructed Tribal Complex to house Tribal government and program operations. 35 jobs created. Complex was dedicated October 1988.

Fiscal Years 1987 thru 1989

Osage Nation of Oklahoma
Pawhuska, Oklahoma

The Osage Nation has received three grants over the past four years from ANA, averaging $80,000 per year for economic development purposes. Subject grantee was successful in establishing a tribal industry thru ANA's seed capital which enabled the tribal council to hire a professional manager to oversee the tribe's assumption of an apparel manufacturing plant. Women's, men's, and children's clothing are produced (from the cutting stage to final production of the specific apparel) for such companies as Polo, Wal Mart, & Bloomingdale's. Seventy-Five (75) jobs have been created, mainly for Native American tribal members: sales over a one year period approximated $600,000. Tribal members have been visited by international delegations of businessmen, and recently the officials of "Osage Ventures" have been invited to France for exploratory wholesale sales of the products. Further, negotiations for garment production for Dept. of Defense is underway.

To sum up, this successful tribal business has resulted in: 1) Employment for 75 person. 2) Top "managerial" slots for 4 tribal members, 3) enhanced tax revenues for tribe's educational and social services.

Fiscal Year 1987

The Baltimore American Indian Center (BAIC) was funded in the amount of $128,392 by the Administration for Native Americans to strengthen employment, training and business development opportunities for the American Indian population of metropolitan Baltimore, Maryland. The Urban Center opened the Inter-Tribal Eat/In Carry Out Restaurant on September 12, 1988, employing 6 people. Eighty-two people, 24 youths, received training in the fast food area. Training consisted of 2 people in the fast food area, 34 cashiers, 13 assistant managers, and four cooks. The rest were general workers. There were 12 people placed in full time jobs that participated in this project. Business assistance was provided to 33 American Indian businesses. These included a tire business, business welder, trash business, pest control, carpet cleaning, landscaping, brick masonry, dry wall, bus service, auto mechanic, roofers, restaurant, chimney sweep, truck driving steel erectors, driving school, house cleaning and vending machines. Three people were assisted in starting their own business, 2 businesses in construction, and one in courier. A total of 57 received jobs from this effort. Thirty-seven families were assisted in finding decent affordable rental housing and provided counseling to 3 families that purchased a house. A 90 page book, brochures, 20 page booklet of short essays and a VHS cassette was developed. An American Indian gift shop was opened, designed to increase public awareness of the contribution of American Indians and to provide additional entrepreneurial and employment opportunities.

Fiscal Year 1988

GRANTEE: Reno-Sparks Indian Colony

PROJECT TITLE: Management Systems for Economic Development

$ FUNDED: 149,766

ECONOMIC BENEFITS & ACHIEVEMENTS RESULTING FROM PROJECT FUNDS FROM ANA.

A grant from ANA assisted the Reno-Sparks Indian Colony of Nevada to establish two business ventures, Sierra Press and Sierra Publishing. Sierra Press - a color separation center, was opened by the tribe in 1986. Sierra Press - a full-service commercial printing establishment, began operating January 13, 1988. On that date the first magazines rolled off the presses. Since then Sierra Press has progressed rapidly, producing major area magazines such as Nevada, Native Nevadan, and Fun and Gaming Magazines. Sierra Press has won approximately $700,000 in printing contracts during FY 1988. Was employing 25 employees at end of grant period.

Fiscal Year 1988

FUNDED: $275,500

Turtle Mountain Band of Chippewa Indians: The Turtle Mountain Band of Chippewa Indians has entered into a tribal joint venture with UniBase Data Entry, Inc. of Salt Lake City, Utah. The newly formed data entry/data processing business is UniBand, Inc., owned 51% by the Tribe and 49% by UniBase. UniBand is located in a 6,000 square foot facility in the Tribal Industrial Park. The initial working capital, management and contract experience, as well as all training has been provided by UniBase. The new firm expects to gain data processing business from local businesses as well as State and local government. They currently have a contract with Federal Express and the Indian Health Service, and have already developed an excellent reputation for quality control on their services.

Fiscal Year 1989

FUNDED: $525,000

Assiniboine-Gros Ventre Tribe of the Fort Belknap Reservation and Chippewa-Cree Tribe of the Rocky Boy's Reservation: A new manufacturing company has been formed from a joint venture between the Fort Belknap Indian community, the Chippewa Cree Tribal Business Committee, and Meissner Tractors, Inc. The new company, Big Bud Manufacturing Co., located in Havre, Montana has purchased the manufacturing plant, land, machines, tools, equipment, jigs and fixtures for its manufacturing processes. Big Bud Manufacturing will build new Big Bud tractors, security window grilles, garbage containers, and other commercial products. Employment for the first year is 40, however the company intends to expand into Defense contracting through its minority ownership and proposed 8 (a) certification. The company anticipates manufacturing heavy equipment under exacting DOD specifications. Ultimately, 200 to 300 people will be employed. ANA played the key role of the Federal agencies involved in this project by leveraging $500,000 from the Bureau of Indian Affairs and $500,000 from the Department of Housing and Urban Development.

Fiscal Year 1989

FUNDED: $111,251

Lincoln Indian Center, Inc.: ANA has provided modest grant funds to the Indian Center, Inc. of Lincoln, Nebraska to set up an Indian Center Housing Corporation. In turn, this Corporation was successful in securing a $918,000 Department of Housing and Urban Development 202 Direct Loan to build a 27 unit complex for elderly and disabled individuals of low income. Occupancy, upon completion of the construction of this complex, is anticipated in October, 1990. The Center is also purchasing and rehabilitating seven duplexes and single-family houses which will be rented to low-income families. The Center has leveraged its highly successful working relationship with the city, Federal government, investment banking firms, and the Center for Community Change to be able to achieve these accomplishments and to plan an expansion of much needed housing over the next five or more years. Future project directions include the purchase of land, starting a for-profit business and 40 additional units of low-income housing.

ANA

Grant Applications Received and Funded

Fiscal Year	Applications Received	Amount Requested	Applications Funded	Amount Awarded
1985	571	97,333,884	247	28,464,760
1986	444	71,643,439	209	27,056,581
1987	389	75,056,581	208	27,620,486
1988	516	79,813,260	224	28,337,057
1989	524	73,155,732	235	28,659,690

MONITORING AND TECHNICAL ASSISTANCE

Question. How many on-site visits for technical assistance, monitoring and auditing were made in FY 1989, and how many are projected for FY 1990 and FY 1991.

Answer. On-Site Visits for Technical Assistance

FY 1988-1989

ANA awarded an 18 month training and technical assistance (T/TA) contract in June 1987 to American Indian Technical Services of Broomfield, CO. Based on information provided by the contractor at the completion of the contract, 764 days of T/TA were delivered under this effort between June 1987 - December 1988. Of these days, the contractor estimated that 550 days were delivered on-site in 38 States. This T/TA is estimated to have been delivered to 120 - 180 Native American tribes/village/organizations eligible for funding under ANA's legislation. (NOTE: Information received from this contractor is incomplete. The Office of Inspector General has been requested by the OHDS Contracts Office to conduct a financial and compliance audit of this contractor, which is in progress).

FYs 1989-1990

During FY 1988, ANA awarded four geographically-based contracts to provide T/TA to Native American entities eligible for funding under ANA's social and economic development strategies (SEDS) program and the OHDS Coordinated Discretionary Funds Program (CDP). Although the first year of these contractual efforts has not been completed, ANA estimates that approximately 200 site visits will be completed by the four contractors in addition to approximately 40 cluster training sessions for multiple groups. The total number of days of T/TA to be delivered during this first contract year is approximately 788 (including both on-site and clustered T/TA).

FYs 1990-1991, 1991-1992

ANA's current T/TA contractual efforts are renewable for a second and third option years. During both of these years, approximately 806 total days of T/TA are expected to be delivered, including approximately 582 days of on-site and 224 days of clustered training sessions.

ANA Staff Monitoring Visits

FY 1988	22
FY 1989	46
FY 1990	50 projected
FY 1991	50 projected

Audits of grantees are handled through the process in the Grants Administration Rules in which each grantee is responsible for the periodic audit of the project according to specific Department of Health and Human Services and Office of Human Development Services requirements.

MAINTENANCE OF EFFORT

Question. Should there be a maintenance of effort provision in the law to ensure that by substituting federal dollars for state dollars, the whole intent of the act is subverted -- i.e., improving and expanding child protective services.

Answer. A maintenance of effort provision for title IV-E administrative costs would be a feasible approach both to slow down the rate of increase of administrative costs as well as to assure that new funds are targeted to improve the administration of the Title IV-E program. There may be a problem in adequately monitoring State adherence to such a requirement.

Administrative costs under title IV-E may not be used to improve and expand child protective services--title IV-B (Child Welfare Services) and title XX (Social Services Block Grant) funds are appropriately used for this purpose.

DATA COLLECTION/FOSTER CARE

Question. Frankly, I am amazed that we are spending over $2.8 billion for AFDC children in foster care and for the child welfare services program -- all designed to improve the quality of the system, and we have no definitive information on what we are getting. If this were a defense contract, the public would be up in arms over the lack of accountability. It was precisely because of the lack of information, that I included language in the FY Fiscal 1990 report directing the Department to promulgate regulations on data collection. What is the status of those regulations?

Answer. We have just recently received approval from OMB for new State reporting forms for expenditures under Payments to States fir Foster Care and Adoption Assistance. States will now be required to submit claims for administrative costs by category of cost activity for the first time, allowing the Office of Human Development Services to analyze and track claims for service-related administrative expenditures versus the more typical administrative costs, such as agency overhead expenses usually associated with managing State programs. We expect to begin receiving useful data by the end of this fiscal year.

GAO REPORT/FOSTER CARE

Question. GAO was critical that there was a lack of educational evaluation and/or assistance as well as a lack of dental and medical care for children in foster care. In short, while the reviews are long on the quantity of the materials required, there is not much attention paid to the quality of care being given. How do you plan to deal with these problem areas?

Answer. Since the initial passage of the law, the emphasis in our reviews has been strict compliance with the requirements of the law. We attempted to judge adherence to what was mandated since these were important new requirements.

We are now in the process of doing two things:

First, we are rethinking and revising the section 427 review process. Under the revised procedures , the review requirements, some of which will have been separated into their components, will not be satisfied with a generic statement by the caseworker addressing the items, but will require specifics and back-up documentation as to how each of the requirements was met. In effect, we will be evaluating the quality of the documentation. The new review process will not evaluate the quality of the services, as such, but will require that attention be given not only to meeting the requirements but to meeting them in a way which will ficus more attention on their purpose.

In addition, we are developing a program review procedure, which is assistance oriented, and which will review the entire child welfare program and make judgments about the quality of many aspects of the child welfare delivery system. These judgments will be backed up by data and information, will be followed by recommendations, and will then be addressed as part of the State's overall child welfare services plan for correction.

Both of these activities will have as part of their focus the newly enacted requirements concerning the educational and medical status of the child.

PLACEMENT OF FOSTER CHILDREN

Question. From all reports, children now coming into the foster care system are harder to place. If, in the past, the bare minimum of services have not been provided -- educational, medical and dental -- how does the Department plan to deal with the provision of services to meet the extraordinary needs of increased numbers of children that have been physically, mentally or sexually abused, or who may even have substance abuse problems?

Answer. The Department is increasingly concerned about the problems facing American families. These problems are more severe than ever before as we see the effects of alcohol and drug abuse. In response, the FY 1991 budget has requested an additional $47 million for the Title IV-B--Child Welfare Services Program. This request is contingent upon enactment of our proposal limiting increases in Title IV-E Foster Care administrative costs. This money would be targeted the expansion and provision of preventive and reunification services which directly affect those problem areas. In addition, we have requested an additional $6 million in discretionary funds for the provision of non-medical services to infants from drug-addicted families.

ORPHANAGES

Question. A recent article in the Washington Post discussed the shortage of foster care parents and the re-emergence of "orphanages." We know from the past, that these "orphanages" were in many cases just warehouses. Is the Department working with the States to develop more effective means of recruitment of foster care families?

Answer. Yes, the Department is undertaking a number of efforts to assist States in developing more effective means of recruiting foster care families. For example, in FY 1989 the Department awarded six grants focused on the recruitment and retention of foster homes. Also in FY 1989, the Department launched an evaluation project dealing with issues currently affecting the recruitment and retention of foster parents. Beyond these efforts, the Department is planning to double discretionary resources in FY 1990 to support competitive grants in the area of foster care.

Additionally, information is disseminated on an ongoing basis regarding alternatives to orphanages in such areas as: (1) in-home services for prevention, reunification and after-care; (2) retention of foster homes; (3) day treatment programs; (4) expansion of specialized family foster care; and (5) the adoption of special needs children.

FOSTER CARE TECHNICAL ASSISTANCE

Question. The Department has been criticized over and again because of its lack of leadership in providing technical assistance and direction to the states. How do you plan to provide this assistance?

Answer. Within the context of available resources, we plan to provide this assistance through a combination of Federal staff leadership and the efficient use of discretionary funds to develop and disseminate good practice materials to the States. We are also revising our section 427 review process to make it more assistance oriented; we are developing a program review system to assist States in assessing their child welfare services programs in relation to national standards; we are announcing a new resource center program to develop and disseminate materials to States; and we are targeting our discretionary resources to demonstrations and models for service delivery in areas of critical interest in the field of child welfare.

PREVENTION/EARLY INTERVENTION STRATEGIES/FOSTER CARE

Question. What steps is the Administration taking to put more resources into less costly prevention and early intervention strategies rather than more expensive foster care?

Answer. We have included as a part of our proposal the addition of $47 million to the funding of Child Welfare Services under title IV-B.

STATE MODEL INTERAGENCY SERVICE COLLABORATION

Question. What is HDS doing to respond to the Senate Appropriations Committee recommendation to demonstrate state model interagency service collaboration on behalf of children with disabilities and their families in state child welfare systems?

Answer. Since FY 1986, HDS has funded a National Resource Institute on Children and Youth with Handicaps which has been charged, in part, with addressing this issue. In addition, we expect to make some FY 1990 funds available to develop a model for interagency collaboration in this area.

CHILD WELFARE REFORMS

Question. Child Welfare reforms enacted in 1980 provided incentives to states to implement certain protections for foster children in order to receive additional child welfare services funds. How effective have these incentives been in encouraging states to reform their programs?

Answer. All States but one are currently receiving incentive funds under section 427 (title IV-B) of the Social Security Act. This means that each of these States has passed a review of its administrative procedures relevant to this section as well as periodic case record surveys confirming that the procedures have been implemented. All States eligible to receive section 427 funds have developed an inventory of children in foster care, a statewide information system, a case review system (case plan, periodic review, and dispositional hearings) applicable to each child in care, and other procedural safeguards and protections affecting foster children and their families.

We recognize that the section 427 review system needs more emphasis on the quality of services to children and families. We have convened a task force which has, over the past few months, developed a revised document for the review of each State's eligibility for section 427 incentive funds. Following comments from both Federal and non-Federal experts, it will be revised and used to prepare Federal regulations relating to the statutory protections.

We believe that States have made progress in reforming their child welfare services programs since the passage of Public Law 96-272 because of the incentives offered in the law. We also believe that more progress will be made as the States and the Federal government work together in the years ahead to make further improvements through joint child welfare planning and the review of programs.

WELFARE REFORM

Question. How effective have these incentives been in increasing the level of resources available for child welfare services, as opposed to foster care maintenance?

Answer. We do not have combined State and Federal figures regarding the amounts that States are spending on child welfare services.

ADOPTION INFORMATION COLLECTION SYSTEM

Question. What is the status of your regulations to create a foster care and adoption information collection system?

Answer. The regulations have been cleared in draft by the Office of Human Development Services and are currently in an expedited Departmental clearance process. They will be published in the Federal Register as a Notice of Proposed Rulemaking by June 1990. We are hoping to have the final rules published in the fall.

Question. How soon will that system be in operation?

Answer. We are expecting to have the final regulations implementing the system published in the fall of 1990. That is one year ahead of the implementation date specified in the law. The system will be in operation by October 1, 1991, as required.

ADOPTION OPPORTUNITIES

Question. Last year, the Congress provided $6,736,000 for Adoption Opportunities for placement of minority children, post legal adoption services, and for speeding up the placement of children legally free for adoption. Are these programs proving effective, and do you have data showing increased placement rates?

Answer. Grants for these purposes were funded in September 1989 for periods of 12, 17 or 24 months. It is too early to determine the effectiveness of the grants or to provide data regarding placement rates.

The following program activities are some examples of grants which have been funded during the past two years to support the placement of minority children:

o The Indiana Department of Public Welfare was funded for a two-year period to provide services to increase the adoptive placement of special needs children. It implemented a One Church, One Child program which is now an on-going program funded by the State with offices in Gary, Muncie and Indianapolis. Three hundred minority special needs children were placed through this program. A licensed child welfare agency has been contracted to provide post-adoption services to the families.

- The Alabama Department of Human Respurces grant, "Expediting Placement of Special Needs Children Through Resource Development" was successful in placing 42 Black children and found homes for total of 115 special needs children. This recruitment program is continuing as a permanent part of the Department's adoption program as the three workers hired for the program were retained.

- Ministers for Adoption - A Black parent group received $4,500 to increase the placement of Black children in Mississippi. Recruitment efforts were conducted in 21 churches in rural counties resulting in 15 Black children being adopted. In addition, 14 families are participating in a newly developed parent group.

- Child-Rite, Inc. - An adoptive parent group in New Mexico that received $2,500 conducted minority recruitment activities focusing on Hispanic, Black and Native American children. Fifty-six inquiries were received: five placements resulted, several placements are pending, and over 15 families were in the home sudy process when the program ended.

- The Georgia Department of Human Resources project, "Promoting and Maintaining Adoptions of Children with Special Needs", planned to place 300 children in a two-year period. The project placed 385 special needs children.

- Boys and Girls Society of Portland, Oregon conducted a state-wide recruitment effort for older special needs children. During the two years of funding, 113 children with special needs were placed for adoption.

The followinig two-year programs were funded in FY 1988 to develop models or refine existing models of post adoption services. These projects will end September 30, 1990.

- The Ohio Bureau of Enrichment developed a manual, Happily Ever After, which provides a model for the provision of support group sessions for adopted adolescents and their parents as well as guidelines for counselors providing post adoption services. Ohio developed a respite care program which provides assistanceto families in crisis.

- DePelchin Children's Center, Texas, established a therapeutically oriented chilren's group for adopted special needs children and siblings which meets the same time as the parent group. During the first year of this program, 20 special needs children were finalized for adoption.

- Lutheran Social Services of Detroit, Michigan developed training modules to increase the awareness of mental health professionals about adoption issues.

- Oregon Department of Human Services provides therapeutic services to adoptive families to prevent disruption. The staff received training to increase their family therapy skills.

- Three Rivers Adoption Council, Pittsburg, Pennsylvania provides training to staff of six mental health centers in Allegheny County; telephone consultation to families in distress; educational sessions for adoptees and adoptive parents; develops and distributes Adoption Matters, a newsbrif covering issues in adoption; and has recruited 43 therapists for a referral network to serve adoptive families.

AGES OF HEAD START CHILDREN

Question. The FY 1991 budget requests an increase of $500 million for expansion of the Head Start program. Your justification states that increases will be used to expand services to four-year olds. Inasmuch as children through age 5 are eligible for Head Start, why are you excluding three and five year olds from participation in a Head Start program.

Answer. There are more than 160,000 three or five-year old children currently enrolled in Head Start. We are not requiring programs to develop policies which will reduce this number. Rather, we are saying that additional children enrolled in Head Start, above those already in the program, should be four-year old children. It is this Administration's goal to make a Head Start experience available to every low-income child in the country prior to the child's entry into kindergarten. Given that most children begin kindergarten at age five, our focus will be in providing Head Start services to these children the year immediately prior to their entry into kindergarten--that is, serving them as four year olds.

HEAD START SALARIES

Question. The FY 1990 conference report included language directing that $50 million be set aside for salaries. Where does the Department currently stand in addressing this problem?

Answer. We are awarding $49,335,000 this year to increase the salaries of Head Start staff. Part of this increase (approximately 60 percent) will be awarded uniformly to all Head Start programs. The remaining funds will be awarded differentially, with programs whose salaries are lower than average receiving greater increases than programs with high salaries. Thus, while the exact increase will vary from program to program, the average salary increase will be 5.4 percent.

HEAD START MONITORING

Question. I note that you have requested $300,000 in Head Start funds to pay for travel expenses in order to monitor Head Start grantees. What type of monitoring will these funds allow, and what will the impact be on Head Start if these funds are not available?

Answer. The $300,000 will enable Federal staff in HDS regional offices to serve as team leaders on monitoring review teams with third of each regions grantees to be monitored each year. This will also allow HDS to fulfill our Federal stewardship responsibility for monitoring Head Start grantees on a routine basis. It will enable us to establish a cycle for all grantees related to the three-year grant application process. All grantees will receive a comprehensive monitoring review during the second year of the three-year grant application cycle, the year before a grantee is refunded for another three years. These activities become especially important in 1991 as monitoring and evaluating grantees selected for expansion will be a key element in ensuring the $500 million expansion is implemented in the most effective and responsible manner.In the past, Federal Head Start staff have competed with other HDS programs for limited travel dollars. This has, for the most part, limited on-site monitoring to grantees with known problems and prohibited routine monitoring of all grantees. Without these funds, monitoring will continue to be limited, with many grantees going for several years without on-site reviews by Federal staff. We believe that routine monitoring by Federal staff is a critical factor in maintaining quality program services to Head Start children and their families.

SPECIAL NEEDS CHILDREN

Question. Both the Senate and House reports accompanying the FY 1990 bill expressed concern over the need to expand training and preparation of Head Start personnel working with special needs children, and accordingly, directed the Department to undertake development of training materials. What is the Department doing to comply with that directive, and will you be working in coordination with the Department of Education's personnel on the development of those materials?

Answer. The Department has just awarded funding supplements of $400,000 to the Head Start Resource Access Projects, agencies funded to provide training to Head Start grantees on the provision of special services to special needs children. These additional funds will be used to develop a new training package incorporating recent research findings on social integration techniques. The package is designed to be used by teachers, administrators, and parents. In addition, the Office of Human Development Services (OHDS) will soon be publishing an announcement in the Federal Register soliciting proposals on developing training materials for mainstreaming special needs children which use state-of-the-art technology. These projects will be funded within the next several months.

The Department regularly shares information with the Department of Education through the Federal Interagency Coordinating Council, which was established to help implement P.L. 99-457. We will continue to work with the Department of Education, through the Coordinating Council, as we develop these training materials.

HEAD START AND CHILD CARE

Question. Given that 80 percent of the Head Start programs operate on a part-day basis, what is currently being done to assist those Head Start families with working parents obtain needed child care services?

Answer. The Head Start Bureau is collaborating with the Family Support Administration to facilitate "wraparound" services and access of Head Start parents to State child care programs, and to promote partnerships in the implementation of the Family Support Act.

The Bureau is also beginning an effort to work with State education agencies to ensure that all children have a pre-school experience, including opportunities for all-day care. Many Head Start grantees and delegate agencies are already engaged in agreements with State and local child care programs. We will endeavor to learn from what is already being done and to expand such services to as many additional children as possible.

STATE FUNDED PRESCHOOL

Question. Currently, more than half of the States fund preschool programs. What is the impact on Head Start of the increase in State-funded preschool programs?

Answer. We are hopeful that the recent growth in State support of pre-school education, much of which is focused on low-income children, will play an important role in our goal of providing all Head Start eligible children an opportunity to participate in a comprehensive child development program before they enter school. Approximately 12 States are providing direct financial support to Head Start programs to enable them to serve additional children or to improve the quality of Head Start through program enhancements such as increasing staff salaries and providing day care services to extend the length of the Head Start day. In other States, children from low-income families are being served through State-supported programs, thereby enabling Head Start to provide its services to additional children. As programs expand there are some issues that require coordinated planning, such as increased competition for qualified staff and facilities.

Question. What is being done to facilitate coordination between these programs and Head Start?

Answer. Head Start has been involved in a number of activities and initiatives designed to encourage coordination between Head Start and sponsoring agencies of State preschool programs. Head Start funded an examination of the effect of the State preschool movement on Head Start which culminated in a report entitled The Challenge of Coordination (May 1988).

Staff in our Regional Offices have been working to coordinate with the sponsoring agencies of State preschool programs within their regions in order to explore planning and coordination activities. In October of 1989, Head Start held a coordination meeting with the State Head Start Associations and Federal Head Start and Family Support Administration (FSA) staff to discuss the need for increased and continuous dialogue and coordination. A follow-up meeting will be held in March 1990 during the National Head Start Association meeting.

Finally, Head Start is planning to provide discretionary grants to an estimated ten States to support programs and activities to coordinate activities between Head Start and State preschool agencies as well as with agencies administering programs under the Family Support Act in each State.

HEAD START REGULATIONS

Question. In December of 1988, regulations were proposed to impose various new requirements on Head Start programs, including limits on class size, teacher requirements, and setting minimum number of days and hours that Head Start programs must operate. What is the status of the regulations and what are the costs associated with the implementation of such regulations?

Answer. The regulations have been redrafted in final form after the review of more than 600 letters containing over 2,500 comments from persons interested in Head Start. Based on these comments, a number of revisions have been made to make the regulation more flexible. We plan to publish the rule in final form within the next several months. The comments generally reflected a belief that this regulation would have a positive impact on the quality of Head Start.

During the past three years, approximately $24.5 million has been used to improve program quality by increasing the length of time programs operate and reducing class sizes. We estimate that the remaining total of implementing the changes proposed in the final rule will cost $8.2 million. It is anticipated that these changes will not be required prior to FY 1991 and will be implemented over a two-year period.

CHILD DEVELOPMENT SCHOLARSHIPS

Question. Provide for the record, the number of Child Development Associate Scholarships awarded in FY 1988 and FY 1989.

Answer. During FY 1988, 2,300 Child Development Associate Scholarships were awarded. As of December 31, 1989 of the 54 participating States, 42 reported that 1,269 scholarships had been awarded during FY 1989. We are expecting the reports from the remaining 12 States within the near future.

Question. Has the Department done any followup to determine whether or not individuals receiving these scholarships have stayed within the Head Start program--if so, what are those statistics telling us?

Answer. There has been no follow-up activity to track the career path of CDA Scholarship Assistance recipients.

However, we do know, based on a 1989 National Survey of Child Development Scholarships conducted by the Council for Early Childhood Professional Recognition, that, of 4,081 respondents who earned their CDA credential during 1985-1988, only 4 percent had left the child care field. These are the multiple reasons for leaving:

95% left because of low salaries;
55% left because of no promotion possibilities;
43% left because of lack of benefits;
34% left because of family changes;
32% left because of being "burned out";
20% left because of personal health reasons; and
11% left because they were not interested in remaining in the child care field anymore

CHILD ABUSE AND NEGLECT

Question. For the past few years, the number of reported incidents of child abuse and neglect have increased. How has the crisis involving substance abusing parents affected these programs?

Answer. While ACYF has no definitive data, anecdotal information from the field indicates that the crisis involving substance abusing parents has resulted in increased abuse and neglect of children. In an effort to explore the implications of this problem for children, the National Center on Child Abuse and Neglect, through its discretionary grant program, funded four, three-year demonstration projects designed to reduce the risk of neglect and abuse in infants born to chemically dependent mothers. Funded in FY 1987 and receiving approximately $100,000 annually, these projects provide parenting skills training and support groups; vocational counseling; drug/alcohol rehabilitation; and social and psychological support.

The expected outcomes of the four demonstration projects include a reduction in the risk of abuse and neglect, incidence of failure to thrive, and injuries and preventable hospitalizations. More positively, expected outcomes also include an improvement in mother/infant interaction, maternal parenting skills and enhanced growth and development of the infant.

The products that will result from these projects include a replicable intervention model to reduce the risk of child abuse and neglect and materials outlining intervention components and techniques. Also, an educational program and a model curriculum to be used by professionals to improve the predictive efficacy of neglect/abuse risk indicators and intervention strategies will be developed. In addition, training materials that address interagency coordination and specialized training for skilled caregivers and foster parents will be developed.

The four demonstration projects are:

- Children's Institute International, Los Angeles, California: An Interagency Collaboration Service and Training Model to Reduce Deleterious Effects of Substance Abuse for Infants Born to Chemically Dependent Mothers
- Southwestern Oregon Community Action, Inc., South Bend, Oregon: Prevention of Abuse and Neglect in Infants of Chemically Dependent Mothers, Prenatal Through Age Two
- Columbia Presbyterian Medical Center, New York, New York: An Intervention Program Designed to Reduce the Risk of Child Abuse and Neglect Among Infants of Chemically Dependent Mothers by Offering Comprehensive Services and Support
- University of Maryland School of Medicine, Department of Pediatrics, Baltimore, Maryland: Prevention and Abuse and Neglect in Infants of Chemically Dependent Mothers - A Special Parent-Infant Care and Enrichment Program.

CHILD ABUSE AND NEGLECT-STATISTICS

Question. What statistics do you keep regarding the number of abuse and neglect cases that involve drugs?

Answer. Current data collection efforts do not provide any statistics regarding the numbers of cases of abuse and neglect that involve drugs. However, some of the above-mentioned grants are involved in collecting such information on their client populations.

CHILD ABUSE AND NEGLECT-STUDIES

Question. Under the 1988 reauthorization of these programs, the National Center for Child Abuse and Neglect was required to conduct four studies on various aspects of child abuse and neglect, with a completion date of April 1990. Where do you currently stand on those studies?

Answer. These studies were all funded by the end of FY 1989, and each will result in a report that includes: the information gathered, an analysis of the information and data, and recommendations on how to better meet the needs of the particular study population. In addition, each report will contain a bibliography and a special literature review with recommendations.

Interim Reports to Congress are due to be sent to the Secretary by April 25, 1990. All of the studies will be completed by September 30, 1991, and final Reports to Congress can be expected by March 31, 1992.

CHALLENGE GRANTS

Question. The Child Abuse Challenge Grants were reauthorized last year. What steps will be taken by the National Center for Child Abuse and Neglect to better coordinate State child abuse efforts under the progress included in the Child Abuse Prevention and Treatment Act?

Answer. The National Center on Child Abuse and Neglect is undertaking a number of efforts to more effectively coordinate State child abuse efforts. For example, a three-day meeting for the State Liaison Officers who coordinate Federal and State child abuse and neglect programs in each State will be held in Washington, D. C. in February. The meeting will focus on the impact of the drug epidemic on child abuse and neglect, and will provide an opportunity both for the exchange of information about activities and programs at the State and Federal levels and the sharing of recent research data and new products developed to respond to the problem of drug exposed children. Similar meetings are also held on a regular basis with State officials responsible for the administration of Challenge Grants and Children's Justice Act Grants to discuss emerging issues. Indeed, in December 1989 the Commissioner for Children, Youth and Families invited all recipients of Challenge Grants to a meeting to discuss the Challenge Grants program and plans for development of further Federal guidance related to implementation of the program.

The National Center is also working to establish uniform grant management procedures for State grant programs. As part of this effort, we are in the process of developing uniform reporting requirements for fiscal and program reports for the three programs.

FAMILY VIOLENCE AND PREVENTION

Question. When the Family Violence Prevention and Services Grant program was reauthorized, a family member abuse information and documentation project was authorized. What is the status of this project?

Answer. In accordance with an interagency agreement the Department of Health and Human Services transferred funds in FY 1989 to the Department of Justice (DOJ), to help carry out such a demonstration project. The Bureau of Justice Statistics (DOJ), as part of a study for the U.S. Consumer Product Safety Commission, sampled 33 hospitals between September 1, 1989 and September 30, 1989, to develop data on individual characteristics relating to family violence, and to objectively document data on the victims of family violence. The data have been coded and tabulated and early matrices are available. A comprehensive analysis of the data will be available by mid-spring.

Question. The reauthorization of this program also included a new program on information and training to encourage law enforcement agencies to work with domestic violence shelters, social service agencies, and hospitals. How has the implementation of this program worked? What types of projects have been funded?

Answer. In accordance with an interagency agreement between the Department of Health and Human Services and the Department of Justice (DOJ), the Office for Victims of Crime (DOJ) made four grants to law enforcement agencies in Rochester, NY; Pueblo, CO; Denver, CO; and Monroe, LA. These grants provided support for training and technical assistance as well as the development of materials and procedures to assist in addressing family violence issues.

RUNAWAY AND HOMELESS YOUTH SHELTERS

Question. The Runaway and Homeless Youth Program is designed to address crisis needs of youth, funding 33 temporary shelters in FY 1989. I have heard from my state of Iowa, and I am told that they are turning away young people who come to the shelters simply because they do not have the room. How many kids are being turned away from shelters because of a lack of space?

Answer. We fund 343 runaway and homeless shelters. Information collected from Federally-funded runaway and homeless youth shelters does not include data on the number of young people turned away for lack of space. However, many shelters are instrumental in identifying other possible shelter options for runaways and homeless youth in crisis when they cannot provide this shelter directly.

Question. Increased funding has been provided for the Runaway and Homeless Youth shelters and first-time funding has been provided to start the new Transitional Living Program. When can we expect that those monies will start to flow to the grantees?

Answer. A solicitation for Runaway and Homeless Youth applications will be published in February. Approximately one-third of the funds will be awarded competitively among agencies with grants expiring this fiscal year and new, first-time applicants. These competitive awards will be made in June and July. Two-thirds of the runaway and homeless youth shelter grantees will receive non-competing continuation grants. Continuation grants will be awarded this Spring and Summer.

The Administration for Children, Youth and Families will announce the availability of Transitional Living Program funds in late March or early April, 1991 and will make the first awards in August. Grants will be awarded competitively, and Transitional Living projects should be operational by the end of the fiscal year.

TECHNICAL ASSISTANCE

Question. Will you be providing technical assistance to new grantees?

Answer. Yes, ACYF intends to award a contract for training and technical assistance for Transitional Living Program grantees. Additionally, in cooperation with the National Youth Resource Center, an ACYF grantee, a manual entitled "Pathways to Adulthood: Strategies To Prepare Youth for Independent Living" was published in May 1988. This manual was provided to all of the Federally-funded runaway and homeless youth shelters and to many other youth-serving agencies as a resource for developing a variety of independent living program models. The manual, and other resources developed by the National Youth Resource Center, will also be available to grantees and other agencies interested in establishing transitional living programs.

CRISIS NURSERIES

Question. Another program that we provided increased funding for was the temporary child care and crisis nurseries program. What is the schedule for getting this money out?

Answer. Under the Temporary Child Care and Crisis Nurseries Program, availability of funds for new awards for FY 1990 will be included in the Coordinated Discretionary Funds Program announcement to be published in the Federal Register in March 1990. Review panels will be convened in June, 1990 and awards made not later than September 30, 1990.

Question. How many grants do you expect to make?

Answer. HDS proposes to award approximately 20 new grants, 10 under each category: temporary child care and crisis nurseries.

ABANDONED INFANTS

Question. We provided first-time funding to start up the Abandoned Infants Assistance Program. What is the schedule for getting this money out?

Answer. The schedule for the Abandoned Infants Assistance Act includes a Federal Register Notice requesting applications to be submitted by April 30, 1990, with grants awarded by September 30.

Question. How many grants do you expect to make?

Answer. The total number of grants will be 45-50, depending on the amount of funding requested.

DEPENDENT CARE PLANNING AND DEVELOPMENT PROGRAM

Question. The FY 1990 appropriation also provided an increase in funding for Dependent Care Planning and Development. Since the inception of the program, how many grants have been made?

Answer. The Dependent Care Planning and Development Program is a State formula grant program. All States and Territories (with the exception of Palau) have elected to participate in this program. The number of grants awarded each FY are as follows:

Fiscal Year	Numbers of States
1986	51
1987	49
1988	52
1989	52

CHILD CARE SERVICES

Question. Of those grants to establish school-age day care programs, how many of those that received grants still provide day care services?

Answer. At the end of each FY, States are required to submit a final report which includes information about the use of the grant, 60 percent of which is for before and after school activities. These reports indicate an increase in the number of mini-grants States are awarding to community and school facilities to establish, develop or improve before and after-school programs. Depending on the size of the State and the amount of the Dependent Care grant award, individual States have reported establishing 10 to 25 new programs annually. In addition, some States have elected to meet the requirements of the grant through means other than awarding grants, i.e., by providing technical assistance, training staff, sponsoring conferences, etc. States are not required to report on the duration of supported programs after the funding year ends.

MONITORING AND/OR TECHNICAL ASSISTANCE

Question. What kinds of monitoring and/or technical assistance do you provide to grantees?

Answer. Again, grantees under the Dependent Care Planning and Development Grant Program are State agencies. All appropriated funds for this program are distributed to States by formula, and ACYF does not have the authority to retain any part of the appropriation for the provision of technical assistance. Technical guidance on the allowable uses of funds and fiscal monitoring of the State grants are provided by Federal staff. Although Departmental guidelines state that the Secretary shall conduct in several States in each fiscal year, investigations of the use of funds received by the States under the Dependent Care Act. No funds are available in the Dependent Care budget to allow for the provision of technical assistance.

DEVELOPMENTAL DISABILITIES 1990 REPORT TO CONGRESS

Question. The 1987 amendments to the Developmental Disabilities Act required each state to prepare a report setting forth the extent and effectiveness of services to persons with developmental disabilities. These reports were to be forwarded to the Secretary by January 15, 1990. What are the major findings resulting from this survey?

Answer. The 1990 State Reports are currently being submitted by the State Governors to the Secretary. The Administration on Developmental Disabilities is in the process of compiling and synthesizing the data from the State Reports. The final report will be summitted to the Secretary in March for transmittal to Congress in April.

DEVELOPMENTAL DISABILITIES BASIC STATE GRANT PROGRAM

Question. Are federal funds appropriated for developmental disabilities programs appropriately focused on addressing major problems in the service system?

Answer. The purpose of the Basic State Grant Program has evolved to the point of planning and effecting policy changes to enhance opportunities for persons with developmental disabilities to become more independent, productive, and socially integrated. Formula grant funds are being used by States to support:

- activities that increase the capacities and resources of public and private nonprofit entities to develop systems which respond to the needs and capabilities of persons with developmental disabilities and their families;
- the conduct of studies and analyses, the gathering of information, development of model policies and procedures, and the presentation of information and recommendations to policymakers that are designed to enhance opportunities for persons with developmental disabilities;
- activities that support systems which provide, make available or find new ways to enhance specialized services or special adaptations of generic services for persons with developmental disabilities;
- demonstrations of effective models and innovative service approaches that increase independence, productivity and integration into the community for persons with developmental disabilities which, if proven successful, can be absorbed and permanently financed by the appropriate State agency;
- outreach activities that enable persons with developmental disabilities to obtain assistance in the Federal priority areas and State priority area in which the State selects to focus its resources and efforts;

- training for persons with developmental disabilities, their family members, professionals, students, volunteers; and

- other activities designed to prevent developmental disabilities from occurring.

DEVELOPMENTAL DISABILITIES PROTECTION AND ADVOCACY ABUSE AND NEGLECT

Question. The 1987 amendments authorized the protection and advocacy systems to investigate incidents of alleged abuse and neglect. Has this authority been used to intervene in the service delivery system?

Answer. The protection and advocacy systems reported for Fiscal Year 1988, the last year for which statistics are complete, that they handled 4,182 cases in which abuse and neglect were alleged or suspected. In those States in which the protection and advocacy systems in the past have encountered barriers to investigate such incidents, this legislative mandate has been an especially welcome assist.

DEVELOPMENTAL DISABILITIES PROTECTION AND ADVOCACY GRIEVANCE PROCEDURES

Question. Have State protection and advocacy systems implemented the grievance procedures mandated in the 1987 amendments, and have these grievance procedures helped obtain access to the appropriate services?

Answer. All protection and advocacy systems have provided assurances to the Secretary that the procedures to allow their clients to pursue any grievances they might have had with the services they received from the protection and advocacy systems have been implemented. The protection and advocacy systems have welcomed the establishment of these grievance procedures. They have believed that it was important that they be held to the same standards of accountability as the service providers with whom they were interacting. Many protection and advocacy systems have developed a written description of how the system works for their clients.

SOCIAL SERVICES BLOCK GRANT

Question. Congress amended the Social Services Block Grant authorizing legislation in 1988 to require more detailed data collection from the states regarding how they use these block grant monies. Where do you currently stand on implementing that data collection, and when will you be able to furnish a report on what the states are doing with this money?

Answer. The Notice of Proposed Rulemaking to implement the new Social Services Block Grant data collection requirements was signed by the Secretary on January 23 and is being reviewed by the Office of Management and Budget.

We expect to publish a final rule late in 1990 or early in 1991 with an effective date of FY 1992. Annual reports for FY 1992 will be submitted by states between October and December 1992. A report on how states are using these funds should be availabe in the Spring of 1993.

Question. Given the extreme flexibility provided to states in administering the SSBG program, what procedures are in place to assure that Federal funds are spent in accordance with the law?

Answer. The major mechanism to assure accountability of Social Services Block Grant (SSBG) funds is the requirement for an annual audit. Under the Single Audit Act, the audit must be conducted by an agency independent of the SSBG agency and must meet General Accounting Office criteria for acceptable financial and compliance auditing.

In addition, we believe the requirement for public participation helps ensure that Federal funds are spent in accordance with the law. Many state and local "watch dog" groups pay particular attention to the state's proposed SSBG plan, including both services and budget allocations, and raise issues with the agency or with the state legislature.

Finally, Office of Human Development Services' staff review pre-expenditure reports to assure that unallowable expenditures are not planned.

INFORMATION, DISSEMINATION, AND MONITORING

Question. OHDS also operates a number of research and demonstration programs. How much of your budget is set aside for dissemination of information obtained from these programs?

Answer. The Office of Human Development Services does not set aside a specific amount of its research and demonstration funds for dissemination activities. However, applicants for research and demonstration grants are encouraged to include a dissemination plan as a component of their applications. In addition, a variety of dissemination and utilization activities have been supported over the past several years.

SUPPORT FOR MONITORING HDS PROGRAMS

Question. How much does this budget request for activities related to monitoring and auditing of the more than $6.9 billion in federal programs?

Answer. The FY 1991 budget request includes $1.3 million for travel. It is estimated that approximately 75% of that amount will be used for activities related to program reviews and monitoring. In addition, about $1.86 million is for contractual arrangements to perform certain onsite and program monitoring functions.

Question. Is this the same amount you requested in your original budget submission, or was that number reduced?

Answer. The amount requested for travel in the original budget submission to the Department was $1.2 million included in Program Direction. The President's FY 1991 budget now has $1 million for travel in the Program Direction account and $300 thousand in the Head Start activity for monitoring, or a total travel request of $1.3 million.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

HEAD START TEACHERS

Question. A 1988 study by the Administration for Children, Youth and Families found that 47 percent of Head Start teachers earn less than $10,000 per year. In 1988, the average annual beginning salary of a Head Start teacher with a B.A. was $12,074 per year (an average of 37% below salaries at local public schools). Are there any estimates of what it would cost to put Head Start teachers' salaries on a par with peers in public schools?

Answer. We do not think the notion of achieving comparability for Head Start teachers requires bringing Head Start salaries to the level of those paid in the public school system. Only a small percentage of Head Start teachers have a four-year degree in early childhood education and even a smaller percentage have the certification required to work as a teacher in a public school system. To measure comparability would require deciding what positions in the community are comparable to that of a Head Start teacher in terms of educational background and required skills. Without a commonly accepted definition of comparability we are not able to calculate the costs of providing Head Start teachers with comparable wages.

Question. Are there any plans to raise these salaries nationwide?

Answer. In FY 1990 Head Start staff were awarded salary increases which averaged 5.4%.

HEAD START FAMILIES/SUBSTANCE ABUSE

Question. Head Start is successful because it is a comprehensive program responding not only to the educational needs of children but also to the social service needs of their families. Head Start staff have expressed concern over the growing number of multi-problem families enrolling in the program. Given the growing drug problem in this country, are Head Start staff adequately trained to deal with this problem?

Answer. Head Start recognizes that substance abuse is a growing problem being experienced by many grantees and that staff must be well trained in how to deal with this problem.

Question. Shouldn't there be more emphasis on training in the areas of drug counseling and education for Head Start parents?.

Answer. There are three areas where Head Start grantees need assistance: working with families and staff who are high risk for substance abuse or who are alcohol or drug dependent; working with children enrolled in the program who are drug affected or drug exposed; and providing that Head Start be part of a community based prevention effort to address the problem of drugs.

Head Start has established a work group to assist grantees in these three areas. This work group will hold its first meeting in early May. We anticipate having a work plan, with specific action steps, by mid-summer. This work plan will, among other things, address the training and technical assistance needs of grantees and how these needs can be met. The plan will also address how Head Start can work collaboratively with other programs and will identify potential resources for grantees to use.

Head Start will also send its grantees a publication later this year which will describe resources currently available for dealing with substance abuse problems and will include technical assistance information designed to help grantees meet the needs of those Head Start children and families affected by substance abuse.

FAMILY VIOLENCE

Question: The incidence of family violence and the need to provide immediate shelter and related assistance to victims and their dependents continue to grow. For FY 1991, you have requested $8,273,000 for family violence prevention, an increase of $54,000 over the 1990 level. What other funds, both in your Department and from other Federal agencies, are currently being used to provide shelter and assistance?

Answer: Federal funds in the Department which may be used to provide shelter and assistance to victims of family violence are: Family Violence Prevention and Services, the Community Services Block Grant, and the Social Servics Block Grant. The Alcohol, Drug Abuse and Mental Health Block Grant may also fund drug prevention and rehabilitation activities for persons involved in family violence. Victims of Crime Assistance funds, administered by the Department of Justice, provide services and assistance to victims of domestic and family violence.

Question: What portion of these funds are used for outreach services for minority women in public housing?

Answer: We have no specific information on outreach services for minority women in public housing. We know from State reports that many communities conduct a wide range of public information and outreach services, including family violence workshops for "women of color."

Question: Given the growing drug problem in this country, are counselors and staff adequately trained to deal with thisproblem? Shouldn't there be more emphasis on training in theareas of drug counseling and education for shelter staff?

Answer: Perpetrators and victims of family violence who are in need of drug rehabilitation are normally referred to agencies that have the relevant expertise in rehabilitation, counseling, and education. Counselors at the shelters are generally able to make informed initial assessments and referrals.

TRANSITIONAL LIVING PROGRAM

Question. In the Anti-Drug Abuse Act of 1988 (P.L. 100-690) a provision was added establishing transitional living projects. What is the status of the transitional living program?

Answer. The transitional living program announcement will be published in the Federal Register in mid-April. The Administration for Children, Youth and Families (ACYF) anticipates that approximately $10 million available in FY 1990 will support 50 to 60 projects that provide a variety of services, including shelter, to homeless youth in their communities. These grants will be awarded in August and September.

Question. Are there models of successful transitional living programs which you can draw on for examples?

Answer. Since FY 1984, the Family and Youth Services Bureau has funded over 25 research and demonstration grants targeted at the development of program models that specifically address the needs of older homeless youth. Funding for those projects totaled over $2.2 million. The general purpose of the grants was to strengthen the capacity of runaway and homeless youth centers to address the problems presented by older homeless youth who were unprepared to live independently.

Specific projects focused on the development of local level, holistic approaches to self-sufficiency including the acquisition of basic life skills; alternative education; employment preparation and placement; health care and treatment; financial management; and housing opportunities.

In addition, in cooperation with the ACYF funded National Youth Resource Center, a manual entitled Pathways to Adulthood: Strategies To Prepare Youth for Independent Living was published in May, 1988. This manual is being used by shelters and other youth serving agencies as a resource for developing a variety of independent living program models.

Question. What arrangements have you made to share this information with the many agencies and groups which are trying to work with gangs?

Answer. The first Youth Gang Drug Prevention projects were funded in September 1989 and have been in operation for six months. Information obtained through program reports and products, as well as the findings of the impact evaluation, will be shared with other groups working on the problem of youth gangs.

Further, the Family and Youth Services Bureau is in the process of awarding a technical assistance contract which will satisfy the provisions of Section 3501 of the Anti-Drug Abuse Act of 1988. This contract will provide information and technical assistance to program grantees and other communities, agencies, and organizations that wish to address the youth gang problem in their localities. It will focus on the implementation of current approaches, assisting groups to plan and organize approaches to the problem, and develop educational and public awareness materials. The contract will also serve as the vehicle for disseminating the information resulting from the grant and evaluation efforts.

OUTREACH AND REFERRAL ACTIVITIES

Question. What kinds of outreach and referral activities are the youth gang projects supporting?

Answer. The youth gang projects are conducting a variety of outreach efforts intended to identify and divert at-risk youth into lawful and productive activities. This early identification and outreach is occurring in both in-school and out-of-school settings, and targeted at 11 to 14 year olds. The efforts include social activities, recreation, tutorial programs, performing arts, employability training, media production, and community volunteer efforts. Participants in these activities include schools, recreation centers, streetworkers, probation officers, churches, businesses, youth clubs, police, and employment agencies.

Referrals are a primary aspect of all of the gang projects. As youth and their families are identified, project staff assess their needs and make appropriate referrals, particularly to drug treatment and rehabilitation services.

ABANDONED INFANTS

Question. Some hospitals and agencies are reporting that the combined medical and housing costs for abandoned infants are running as high as $100,000 per child. How does the Department plan to help these children, given the amount of money requested for this program?

Answer. For FY 1991, the budget includes $10 million for the Abandoned Infants program, and $6 million for a new initiative to address the unique problems of children born to crack-cocaine using and HIV infected mothers. The amount requested will enable the continued funding of a number of special model service coordination and coordinated service delivery programs. It is our understanding that infants become "boarder babies", with consequent high medical and housing costs because the child and family welfare system is unable to respond promptly, when a hospital informs them that an infant is in need of substitute care. The hospital must then keep the child for an additional, sometimes very lengthy, period of time. We are convinced that the technology necessary to solve this problem is readily available. There are successful programs focusing on the recruitment, training and support of foster parents, which are available for dissemination. In addition, much closer coordination between the hospitals and child and family services programs is needed to greatly reduce, if not eliminate, the time gap before foster placement is possible. These issues will be addressed in the model service programs.

Question. Will the projects funded under this program be coordinated with other Federal and/or State programs that serve the same population?

Answer. All programs funded under the Abandoned Infants Assistance Act will be required to provide evidence of coordination with all related State, Federal, local, public and private programs serving this population.

DEMONSTRATION PROGRAMS

Question. Given the numbers of infants and young children who could possibly qualify for Abandoned Infants Assistance services and the limited resources you have requested what criteria will you use to structure these demonstration programs?

Answer. These grants will be awarded based on criteria which will include the quality of the proposed project, the expertise of the staff, the number of children to be served and the severity of their problems as well as the costs associated with the assistance provided.

ABANDONED INFANTS ASSISTANCE ACT

Question. The Abandoned Infants Assistance Act requires that the Secretary of Health and Human Services conduct a study to determine how many infants and young children are abandoned each year. When will this study be undertaken?

Answer. We expect to have this study implemented by July 1, 1990, and we should have a final report available to Congress by April 1, 1991.

YOUTH GANG DRUG PREVENTION ACTIVITIES

Question. Youth gang drug abuse prevention activities are provided by a number of agencies and programs that serve young people, such as schools, the juvenile justice system, employment agencies, and other social service providers. What type of coordination exists among these various agencies and programs?

Answer. The coordination and collaboration of the above listed agencies and others (i.e., police departments, housing authorities, voluntary youth-serving agencies, and neighborhood organizations) is the focal point of the Youth Gang Drug Prevention Program. Sixteen community-based consortia grants, totaling over $10 million, were awarded in FY 1989 to formalize and structure collaboration between these groups so that comprehensive services and supports would be available to at-risk youth. Each grantee has a mix of organizations, and a specific work plan which supports and coordinates with the work of the other members of the consortia. In most instances, case management procedures are being used to oversee the services that are received by youth coming in contact with any of the member agencies.

Similar, yet less formal, collaborations are occurring in another 36 youth gang grants funded by the Administration for Children, Youth and Families during fiscal year 1989. Many of these grants were also made to the types of agencies and programs described above.

YOUTH GANG DRUG/EVALUATION PLANS

Question. What types of evaluations are being carried out on the Youth Gang Drug Abuse Prevention Program to measure their effectiveness?

Answer. Each grantee has been required to implement its own evaluation plan. In addition, the Family and Youth Services Bureau will soon be awarding a two-year Impact Evaluation contract to assess the effectiveness of the gang projects. The particular focus of this evaluation will be the consortia projects, with a view to assessing the effectiveness of the formal collaborative approach in reducing at-risk youth involvement in gangs.

OFFICE OF INSPECTOR GENERAL

STATEMENT OF RICHARD P. KUSSEROW, INSPECTOR GENERAL

BUDGET REQUEST

Senator HARKIN. The next witness is Mr. Richard Kusserow, the inspector general of the Department of Health and Human Services. Mr. Kusserow has served since 1981 as inspector general for this Department. With his help last year we identified several areas where excess government spending could be reduced without impacting on the beneficiaries of health programs.

We introduced legislation to achieve some of the savings and have been able to cut some unnecessary spending further in the fiscal year 1990 Labor-HHS bill. But it is a new year and we are committed in doing even more and finding more inefficiencies if we can, wherever we can.

So, welcome back to the subcommittee, Mr. Kusserow. Again, let me compliment you and commend you on doing an outstanding job at the Department. I think that you have conducted the inspector general's office in a way that should set the standard for a lot of other departments.

We were talking about you the other day with the Labor Department.

Mr. KUSSEROW. I hope you are not suggesting that I go to Labor. [Laughter.]

Senator HARKIN. Well, we need somebody over there like you. We need somebody over there with the same kind of attitude and expertise that you have.

So, again, welcome. Your statement will be made a part of the record. Please, proceed.

SUMMARY STATEMENT

Mr. KUSSEROW. Thank you, Mr. Chairman. I will submit that for the record, and I will highlight a few points from our budget submission.

First of all, our budget proposal for fiscal year 1991 maintains the current 1990 FTE level of 1,415 FTE and requests and increase in obligations of only 1.1 percent. This increase would partially offset some of the mandatory cost increases that we will have because of pay raises, FERS, rent, and so forth. We will, in fact, absorb $1,570,000 in other built-in costs that have occurred over the last year.

You mentioned the Department of Labor. It is interesting to know that our Department's budget has been increasing on an annual basis more than the entire budget of the Department of Labor, or even HUD.

And yet those Departments' inspectors general have staffs of about 500 people that focus just on what our incremental increase is each year. That kind of puts things back into perspective.

In fiscal year 1989, we continued to have a payback on the money invested in our budget. It was about $66 for every dollar appropriated for us, and we are pleased that our cost effectiveness is continuing.

In 1988 when we came before this committee, we were very proud of the fact that we had fines, savings, restitutions, and recoveries of about $5.5 billion. We increased that for 1989 by $130 million, bringing total savings up to nearly $5.7 billion. We are pleased that we are still able to produce a good return for the invested dollar.

We have documented savings of about $4.25 million for each OIG FTE. This statistic also continues to improve.

This last year, we convicted in the U.S. district courts 1,278 individuals and entities nationwide who had committed fraud or abuse against our programs or beneficiaries.

In addition to that, as a result of a host of new sanction authorities that the last two Congresses have put into effect to protect beneficiaries against abuse of individuals or through the program, we had an 81-percent increase in the number of administrative and civil prosecutions of individuals who in fact behaved so badly as to warrant sanctions.

We have been able to increase our accomplishments because of the help we have received from the Congress. I would be remiss in not mentioning that a lot of the savings come about as a result of work by you, this committee, and the Congress as a whole. The Omnibus Budget Reconciliation Act of 1989 resulted in savings of about $10 billion in the Medicare Program alone.

About $8.5 billion of that amount we contributed with our reports and efforts to provide the kind of information that allow policymakers, both in the executive branch as well as in the Congress, to begin to move to effect savings and to curtail the rate of increases in outlays in our programs.

Since our last appearance before you, Mr. Chairman, we have had a major midcourse correction in terms of our work plan and assignment of resources. Last year when I was before you, I discussed the major buildup in program dollars and issues to be faced in the Medicare Catastrophic Insurance Program. Although the catastrophic program has been repealed, we have a number of new issues that have come onto the scene.

First of all, we have seen Congress engage in physician reimbursement reform, which has created a lot more work for us. We have had the whole Medicare secondary payer issue really burgeon into a major problem, which we are now estimating to be in excess of $.5 billion of losses to the trust funds each year. We also have 16 different projects planned or underway to assess and implement the JOBS Program under the Family Support Act amendments. These are but two examples of new work underway which can now be accomplished with staff freed up from the repeal of the catastrophic program.

PREPARED STATEMENT

I do not want to use up my allotted time by simply recounting all of the activities we accomplished this last year or have planned for fiscal year 1990 and fiscal year 1991. I would prefer, Mr. Chairman, to reserve my time to answer questions that you might have about our budget or our program.

[The statement follows:]

STATEMENT OF RICHARD P. KUSSEROW

Good morning Mr. Chairman, I am Richard P. Kusserow, Inspector General of the Department of Health and Human Services. I am pleased to appear before you today to present the FY 1991 appropriations request for the Office of Inspector General (OIG). As you know, our statutory mission is to eliminate waste, fraud and abuse in the Department's programs and to protect those beneficiaries whose health and welfare depend on them. The resources requested for FY 1991 will enable us to continue to fulfill that mission.

ACCOMPLISHMENTS

Before describing some of our goals and objectives for the coming year, I would like to thank you for your assistance with our past fiscal year appropriations. You can be assured that those additional resources you supported have been and will be put to good use. In FY 1989, we recorded our ninth consecutive increase in savings and prosecutorial accomplishments. Other significant accomplishments include: identification of 21 material weaknesses in program internal controls; improvements in the Department's internal control program; our generic drug investigations; our work in the areas of Medicare as secondary payer; and child support enforcement.

During FY 1989, $5,689,000,000 in settlements, fines, restitutions, receivables and savings resulted from OIG activities and implementation of OIG recommendations. Our most impressive growth came in the area of administrative sanctions effected, in which we imposed 846 sanctions on individuals and entities who defrauded or abused departmental programs or their beneficiaries. This represents an increase of 117 percent since 1985. In addition, our investigative staffs' efforts resulted in a record 1,278 successful judicial prosecutions.

The OIG's role in the Department's internal control program includes advising top management on internal control issues, analyzing the Department's process for evaluating internal controls, and reviewing the Department's annual report to the President and the

Congress on the status of internal control weaknesses. During FY 1989, the OIG identified 21 of the 25 material weaknesses which were included in the Secretary's report to the President and the Congress as required under the Federal Managers' Financial Integrity Act (FMFIA).

In addition, we are proud to be producing for the third time our Cost Savers and Management Improvement Recommendations handbooks. These books, commonly referred to as the Red and Orange book respectively, reflect either where funds could be put to better use or where we believe, based on our work, management improvements are needed in the Department's programs. Our Red book lists recommendations which could result in over $16 billion in savings. Other OIG activities result in the identification of questioned costs (costs which are challenged because of a violation of law, regulation, grant, etc.) and unsupported costs (those costs which are not supported by adequate documentation). The OIG also performs a number of functions that cannot be quantitatively measured. Our primary activity in this area is the execution of short term evaluation studies which assess complex qualitative aspects of the Department's programs. These studies are frequently requested by high level departmental executives and Members of the Congress and result in rapid, accurate and up-to-date information. Examples of this work include audits and inspections on cholesterol screening, hospital patient dumping, hospital closures, hospital profits, Social Security and Medicare client satisfaction, independent laboratories, Medicare reimbursement issues, physician ownership of health care facilities, and youth drug education programs. These types of studies give departmental managers and congressional law-makers timely information needed in their decision-making process.

BUDGET REQUEST

Our FY 1991 budget request includes resources for 1,415 FTEs, which is the same as our FY 1990 level. For FY 1991, we are requesting $95,223,000 in obligational authority, of which $51,500,000 would be from FY 1991 appropriations. Additionally, $43,723,000 would be transferred from the Medicare and Social Security trust funds for work in support *of these programs. Our FY 1991 request is a 1.1 percent increase above the FY 1990 level. We have not requested additional FTEs in FY 1991 and only a marginal increase in obligational authority. We will accomplish our goals and objectives by shifting existing resources which are no longer needed to monitor the Catastrophic program. Many of these pertain to critical issues confronting the Department and will assist in attaining the Secretary's goals and objectives. I would like to briefly describe some of these goals.*

FMFIA

For the coming year, we will continue our emphasis on ensuring that effective managerial internal controls are in place among the multitude of programs within the Department. The most effective way to prevent incidents of fraud, waste and mismanagement from occurring in the Department is to ensure that effective management controls are in place and to ensure that established policies and procedures are consistently followed.

While all managers are responsible under the FMFIA for identifying potential for loss, for establishing and assessing controls and safeguards where needed, the OIG provides the leadership, oversight and guidance needed to ensure that a system of checks and balance are in place. Audits, inspections and other reviews conducted by OIG, while not a substitute for management controls, complement an effective management program for prevention and early detection of fraud and mismanagement.

Medicare as Secondary Payer

The OIG will continue its efforts to eliminate billings to Medicare which violate the Medicare secondary payer (MSP) provisions. Numerous studies conducted by OIG and the General Accounting Office have demonstrated that, despite legislation making Medicare the secondary payer, Medicare continues to be billed as primary payer. Recent court cases have affirmed our position that private companies are liable for those claims which they should have paid under the MSP provisions. We will audit selected insurance companies and fiscal intermediaries to determine if they are complying with MSP provisions and will assess contractor procedures to ensure that all appropriate Medicare payments are identified and processed in a timely and accurate manner.

Public Health Service

We plan to focus on new activities in the Public Health Service and will conduct audits and inspections of issues pertaining to acquired immune deficiency syndrome (AIDS), biomedical research, scientific misconduct, and substance abuse. We will also focus particular attention on the Food and Drug Administration programs in view of recent problems associated with generic drugs and medical devices.

Physician Payment Reform

We also plan extensive monitoring and oversight activities related to the implementation of the recently enacted resource-based relative value scale for physician reimbursements. This change in physician reimbursement was included in the Omnibus Budget Reconciliation Act of 1989 (Public Law 101-239) and represents the most significant change to the Medicare program since the enactment of the prospective payment system (PPS) in 1983.

Sanction Authorities

During the past 5 years, the Congress has vastly expanded the sanction authorities which the OIG is charged with enforcing - an expansion of approximately 60 authorities. The majority of these authorities were contained in the Medicare and Medicaid Patient and Program Protection Act of 1987 (Public Law 100-93), the Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203), the Omnibus Budget Reconciliation Act of 1989 (Public Law 101-239), and various provisions retained from Public Law 100-360.

During 1990, OIG anticipates promulgating regulations implementing many of these new authorities and has already begun enforcing these authorities. Final regulations are being developed to address the emergency care anti-dumping provisions, the Medicare anti-kickback "safe harbor" provisions and penalties resulting from violations of the National

Practitioner Data Bank. A comprehensive proposed regulation package addressing a variety of new OIG exclusion and civil monetary penalty authorities, resulting from Public Law 100-93, will also be published shortly for public comment. The increase in OIG sanction activity is dramatically illustrated in the 846 sanctions imposed in FY 1989. In addition, we plan to maintain our criminal investigations in all the Department's programs.

Family Support Act

In addition, we plan a number of studies related to monitoring the implementation of the Family Support Act of 1988 (Public Law 100-485), including an evaluation of paternity establishment methods, effectiveness of the JOBS program and availability of child care facilities.

CONCLUSION

Funding spent on the Office of Inspector General is a sound investment. In FY 1989, each dollar invested in our office resulted in savings of over $66. We are proud of our statistical accomplishments and the successes we have had in ensuring that beneficiaries receive quality care, that the integrity of the trust funds are maintained, and that those individuals who defraud the Department's programs are held accountable for their actions. The resources that we have requested for FY 1991 will enable us to continue to maintain our statistical accomplishments, and carry out our commitment to protect the Department's programs and the health and welfare of the beneficiaries of those programs.

BIOGRAPHY OF RICHARD P. KUSSEROW

Richard P. Kusserow was nominated Inspector General of the U.S. Department of Health and Human Services by the President in April of 1981 and confirmed by the Senate in June.

As Inspector General of the Department, he is charged with the statutory responsibility to ferret out fraud, waste, abuse and inefficiency in the world's largest agency. This department has some 250 health and human services programs and a budget of nearly one-half trillion dollars which represents over one-third of the federal budget.

Kusserow directs a staff of 1,400 auditors, inspectors, program analysts and investigators. His office recorded more than $5 billion in fines, savings, restitutions, recoveries and settlements in the last year. This represents a 3,500 percent increase during his tenure. Since 1981, convictions resulting from his investigative staff rose from 165 to nearly 1,300, an 800 percent increase. Additionally, he has increased successful administrative sanctions in excess of 1,000 percent against health providers and suppliers. He has "kicked out" over 2,500 individuals and entities from the Medicare and Medicaid programs for abusive or fraudulent behavior against the beneficiaries or programs.

Kusserow served from 1985 to 1989 as the Vice Chairman of the President's Council on Integrity and Efficiency (PCIE). The PCIE, created in 1981 by President Reagan, provides cohesive leadership to governmentwide activities

to reduce fraud, waste and abuse in federal programs and operations. The Vice Chairman's role includes the responsibility for coordinating and tracking all governmentwide Inspector General projects; managing the preparation of the President's semiannual report on the accumulated accomplishments of all Inspectors General; coordinating efforts with the President's Council on Management Improvement; and, serving as liaison for all Inspectors General with the Office of Management and Budget.

He is a member of the Attorney General's Economic Crime Council and was appointed by President Bush to serve on the National Advisory Commission on Law Enforcement. Kusserow is president-elect of the National Association of Government Accountants (AGA) and past-president of the Baltimore Chapter of AGA. Since 1985, he has served on the AGA Task Force on Federal Financial Management. He also serves as the Federal representative to the National Intergovernmental Audit Forum. On July 1, 1987, he received the National Distinguished Leadership Award for sustained outstanding leadership and notable contributions in the field of financial management from the National Association of Government Accountants. He was twice elected national president of the Association of Federal Investigators and is an active member of the Society of Former FBI Agents, and the American Society of Industrial Security.

He earned his bachelor's degree from UCLA, followed by postgraduate work at Southern Methodist University and John Marshall University School of Law. He earned a master's degree from California State University at Los Angeles where he was also employed as a lecturer in government.

Kusserow served in the United States Marine Corps and was honorably discharged as a captain. He was an intelligence officer with the Central Intelligence Agency (CIA) before moving to the Federal Bureau of Investigation (FBI) in 1969. As an FBI agent, he worked in Pennsylvania, Washington, D.C., West Virginia and Chicago. He acted as the coordinating supervisor for nine squads of agents constituting the Chicago FBI Organized Crime program preceding his appointment as inspector general.

He has lectured widely and written numerous articles on innovative investigative and management techniques on fraud and corruption in government programs. He is co-author of the book entitled "Management Principles for Asset Protection."

HEALTH EDUCATION ASSISTANCE LOAN PROGRAM

Senator Harkin. It has been estimated that savings of almost $75 million a year could be realized through curbing the growth of defaults in the Health Education Assistance Loan Program.

Mr. Kusserow. Correct.

Senator Harkin. Do you have specific steps you recommend to do this?

Mr. Kusserow. Yes; in fact, we have an outline of those steps that I would be more than pleased to make available to the committee.

HEAL Program Savings

The Office of Inspector General (OIG) has made numerous recommendations for reducing the default rate in the Health Education Assistance Loan (HEAL) program. These have included recommendations related to "due diligence" requirements, which have since been implemented by the Public Health Service (PHS). OIG has also made the following unimplemented recommendations.

Limit the Federal grantee to 80 percent of the loan (20 percent cost-sharing by the lender).

Permit lenders to require co-signers.

Eliminate the Federal responsibility for loan amounts which go into default because of death or disability, and allow lenders to impose a fee to protect themselves against such eventualities.

Provide a uniform statute of limitations of six years for action by a lender against a defaulted borrower. This would encourage lenders to act more expeditiously in pursuing due diligence.

In addition to the above, OIG has also made the following recommendations involving enhanced revenues to SLIF (the Student Loan Insurance Fund). These recommendations may have an indirect effect on the HEAL default rate.

Eliminate the current 8 percent ceiling on insurance premiums, charge insurance premiums over the life of the loans, and link insurance premium assessments to default rates in various health disciplines, schools, and lenders (e.g., the higher the default rate, the higher the insurance premium).

Raise the insurance premium rate to an actuarially sound figure. Periodically adjust the premium rate to maintain the viability of SLIF.

Make payments on delinquent loans as necessary to keep the would-be defaulted loans current, rather than waiting until they go into default and then paying the full amount of the defaulted loans plus interest.

Sell "cured loans" (once in default and now in repayment status) to the secondary market, including "Sallie Mae".

Seek authority to limit eligibility for HEAL assistance to U.S. citizens. The HEAL program was not designed to underwrite the medical education of the entire world—its purpose is to assist in the education of physicians for the American public. Foreign nationals coming to the U.S. for medical education are, by law, not permitted to remain here in order to become licensed and establish a practice. Yet, many foreign students do participate in the program and remain in the United States. Even worse for the program those that return to their native countries have an extremely poor record of repayment and thus create a high default rate. There is no way these defaulted individuals can be made to pay.

DEFAULTS IN HEAL PROGRAM

Senator HARKIN. The Public Health Service has been unable so far to project future defaults. So how do you get this figure of $75 million?

Mr. KUSSEROW. We have been looking at the cause of the continuing problem in that arena. I think that it is nothing more than a glorified ponsi scheme, where we continue to infuse more money into the program to keep it afloat.

I think we have to look at why we have defaults. A lot depends upon what kind of investment we have in health practitioners of the future. We find, for example, a lot of the physicians and dentists are able to go through private programs to get an equal kind of assistance that we would provide. And we have other specialties which do not have as good a payback reputation.

We have been able to review the history of all these programs. Based upon reviewing the internal controls, we feel that we can, in fact, make some marked improvements in the expenditures.

LABORATORY TEST REIMBURSEMENTS

Senator HARKIN. Mr. Kusserow, this chart up here on the left illustrates what we are paying out for lab tests. The red line is what physicians pay and the blue line is what Medicare pays for the same lab tests. So, you can see lab A on the far left, the physician paid about $30 there. And Medicare—for the same lab test, same lab—paid $51 or $52. The same is true all across there.

Is there any valid argument on the part of the lab for charging Medicare more than they are charging private physicians?

Mr. KUSSEROW. Well, we have a series of studies we are conducting in the area of clinical laboratory work. We have looked at physician-operated laboratories, clinical laboratories, and reference laboratories. We did a lot of the testimony leading up to the Clinical Laboratory Improvement Act, or CLIA, in 1988.

We found that there were qualitative differences in tests performed by physicians and clinical labs. You could not take the average test performed by a physician and have the same degree of assurance of quality that you would in the same test performed by a clinical laboratory. This difference in quality could explain the discrepancy in fees charged by the two. That problem has been dealt with by the CLIA 1988 legislation.

What CLIA does is set a uniform standard for the performing of tests. Now, if the standards are uniform, you could expect that the results would be fairly equivalent, and that the payments should then also be similar.

Senator HARKIN. As I understand it, checking with my staff here, if you take lab A, the one on the far left side, what that represents is what lab A would charge the physician for a test.

Mr. KUSSEROW. Oh, I am sorry, I misunderstood. I thought you were looking at tests performed by a physician versus those performed by a clinical laboratory.

Senator HARKIN. They would charge the physicians the red line for that test, they would charge Medicare the blue line——

Mr. KUSSEROW. Then you have a different wrinkle. And that is, within the system what you do not want to have is the benefit of self-referral. You do not want to have physicians benefitting from referring laboratory work either to themselves or to a lab that they have a financial interest in.

What you may have in trying to guard against abuses in the system is the perception of creating an injustice. But in terms of these specific laboratories and physician rates, if you would like, I would be happy to analyze them and come back to you with the results of that analysis, looking at the exact data and giving you exact answers.

DISCREPANCIES IN PAYMENT RATES

Senator HARKIN. We are going to ask HCFA about this, too. But basically we got this information out of the Inspector General's Office. But we will work with you on——

Mr. KUSSEROW. We have done work in the area.

Senator HARKIN. But it is an area in which I have developed an interest since I have taken over the subcommittee. I have seen more and more reports about how labs really are charging Medicare a lot more than what they are charging doctors. Is it a fact that labs are charging doctors less than what it costs to do the tests?

Mr. KUSSEROW. No; the differential is typical of what you find in the industry. And the recommendation that we have proposed is that HCFA seek legislation to bring payments more in line with each other. You should not have a differential as you have here between the red bars and the blue bars. These payment rates should be the same.

Senator HARKIN. They should be the same.

Mr. KUSSEROW. Yes.

Senator HARKIN. Do you have some recommendations on how to close that gap?

Mr. KUSSEROW. Yes; we do. In fact, what I can do is give you the audit report in which we examined the differential which led to the recommendation we made to the Health Care Financing Administration that they should explore legislation to remove that discrepancy.

Senator HARKIN. We will bring this up with HCFA, but, since you are here I will mention it to you. We got the restriction on competitive bidding lifted last year.

Mr. KUSSEROW. That is right.

Senator **Harkin**. And I would hope that you would start taking a look and see what is happening in those areas—in those places where they are competitively bidding.

Mr. **Kusserow**. We are, in fact. We should be paying at the lowest charge level, not the highest.

RECOVERY OF SOCIAL SECURITY OVERPAYMENTS

Senator **Harkin**. One last thing, the recovery of Social Security overpayments. You estimated that the Social Security Administration, could save over $1 billion in the next 20 years by allowing the recovery of delinquent overpayments at the higher of the amount of interest income lost to the trust funds or the value lost to the trust funds due to inflation. In other words, on the higher of those two amounts.

Mr. **Kusserow**. That is correct.

Senator **Harkin**. My only question is, can this be accomplished administratively, or do we have to pass legislation?

Mr. **Kusserow**. Administratively. Although I would confess there is some internal dispute in the Department about that.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. Well, we have to find out because if we have to do something, we will do it here. Mr. Kusserow, we have some other questions that we might want to submit to you just in writing.

But, again, congratulations, and keep up the good work. And anyway that we can—if we have to help here in anyway legislatively, let us know.

Mr. **Kusserow**. Thank you, Mr. Chairman.

Senator **Harkin**. Thank you, Mr. Kusserow.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

ATTORNEY FEES

Question. In January 1987, the Office of Inspector General, HHS, issued a report that found that attorneys representing social security claimants were routinely receiving fees that were equivalent to very high hourly rates. This report led to administrative action by SSA to limit the amount of the fee that could be approved by administrative law judges (ALJs). The OBRA of 1987 restored the amount that could be approved by ALJs to their former levels, and required SSA to conduct a broad study of the problem. SSA released its report in July 1988.

Has the Office of Inspector General (OIG) done any recent studies on this problem?

Answer. Subsequent to its administrative action to limit the amount of the fee that could be approved by ALJs, SSA requested the OIG to conduct an inspection to determine whether claimants were having problems in obtaining attorney representation. The OIG conducted a program inspection and issued a final report in August 1988. Findings included 1) the vast majority of Title II claimants who request hearings are not having any difficulty obtaining attorneys, and 2) attorneys willingly take SSA cases. The OIG recommended that 1) SSA should continue to support its current attorney fee payment policy because it is less costly to claimants than a (then) pending legislative proposal that would mandate automatic 25 percent fees, and 2) SSA should assure that all hearing offices properly inform claimants about their rights to attorneys and about attorney fee arrangements.

SSA used the information from the OIG report in its report to Congress required by the OBRA of 1987. We have done no further work in this area.

ANTI-KICKBACK REGULATIONS

Question. What is the status of the Medicare/Medicaid anti-kickback regulations that came out in proposed form on January 23, 1989? What effect will the new OBRA 1989 self-referral provisions have on the regulations?

Answer. As a result of the 60-day comment period following the publication of the proposed rule, the OIG received in excess of 800 public comments. The OIG has completed its full analysis of these comments, and has developed both a final regulations package, addressing the various safe harbor concerns set forth in the January 23, 1989, Notice of Proposed Rulemaking (NPRM), and a new proposed rule that expands safe harbor consideration to several additional area. These additional areas encompass revisions to the investment interest safe harbor provision; price reductions offered to group plans; practitioner recruitment; malpractice insurance; cross-referral agreements; cooperative hospital service organizations; and exclusive ownership control.

Both documents remain in Departmental clearance and await both OMB and Department of Justice (DOJ) review and clearance prior to their publication in the Federal Register.

With respect to what effect the new OBRA 1989 self-referral provisions may have on these regulations, section 6204 of P.L. 101-239 is designed to limit physician ownership and referrals related to clinical laboratory services, and should be viewed as a different approach to dealing with similar concerns.

Section 6204 of P.L. 101-239, the Omnibus Budget Reconciliation Act of 1989, establishes new sanctions and civil money penalties regarding prohibited arrangements in the area of clinical laboratory services. The statute is intended to protect the Medicare and State health care programs from the stifling effects of dishonest influence caused by kickbacks, rebates and other illicit payments. The statute itself makes specific conduct illegal. On the other hand, the task of the OIG in developing the safe harbor provisions is to specify various payment practices which will not be considered kickbacks for the purpose of criminal prosecution or program exclusion. The safe harbor regulations are not intended to define criminal action, but rather establish certain standards and guidelines that, if met, will protect the individual or entity from criminal or civil penalty.

The new statutory authority under section 6204 sets forth a legal deadline of October 1, 1990, for promulgating final regulations on that provision.

PEER REVIEW ORGANIZATIONS

Question. The Inspector General has criticized the efficiency of PROs in the past. How would your office evaluate the PRO program now, especially in its quality assurance role?

Answer. In response to the Senate Committee, subsequent to the Inspector General's report on peer review organization (PRO) activities, the Health Care Financing Administration (HCFA) instituted controls in the quality assurance area. Since that time, the problems identified previously have improved. Through the PRO Monitoring Protocol and Tracking System (PROMPTS) the discrepancies in quality review studies between SuperPRO, PROs, and intermediaries have narrowed. The OIG is currently doing a follow up study of the quality assurance area and should issue a report by the end of calendar year 1990.

Question. Are there any changes that you would make to improve the ability of the Inspector General's office to carry out the PRO sanction process?

Answer. Yes. However, first we would like to describe some actions we have taken internally to improve the process.

We conducted our own internal review of the Department's PRO sanction procedures and have taken actions to improve the coordination between the PROs and State licensing boards. We have modified the regulations to require that PROs disclose "violations-related" information with State licensing boards. We also send a copy of each sanction notice to the State licensing boards with a request that they conduct their own reviews to determine whether action should be taken to revoke, restrict or suspend the licenses.

In addition, there are two legislative proposals pertaining to the sanction process pending in the Department which we would like to see enacted into law.

The first proposal would eliminate the necessity under current law that the PRO show not only that poor quality or unnecessary care was provided but that such care was accompanied by an unwillingness or lack of ability on the part of the provider. Under the prior PRO statute, a failure to comply with the specified statutory violations was considered evidence of a practitioner's or provider's unwillingness or lack of ability to comply with these requirements. Accordingly, the Department did not have to make a separate, independent finding on the unwillingness/inability issue. The current structure of section

1156 creates unnecessary obstacles to the sanctioning of health care practitioners and providers failing to comply with the statutory obligations.

The second proposal would consolidate and make uniform the OIG civil monetary penalty (CMP) authorities by standardizing the amounts of the penalties and the procedures. The Social Security Act currently sets forth a myriad of civil monetary penalty authorities upon which the OIG may levy penalty amounts against health care providers and practitioners, as well as other individuals, for specified violations or misconduct. The circumstances and criteria for imposing penalties, their relationship to OIG's exclusion authorities, and the maximum dollar amounts up to which penalties may be imposed vary significantly, with no clear indication or rationale for the differences that exist. We support the Department's proposal to make the OIG's CMP authorities more consistent, cohesive, uniform, and orderly by: adopting two standards of knowledge; raising some penalty amounts; authorizing assessments for all CMPs of up to three times the amount claimed or charged in violation of the CMP provision, and for the costs of bringing a civil action; authorizing exclusions for all CMPs, except for CMPs which are intermediate sanctions against providers substantially out of compliance with program requirements; and consolidating CMP authorities under Title XI of the Social Security Act.

COST-SAVER RECOMMENDATIONS

Question. Please identify the 5 or so most important "cost saver" recommendations made by the OIG in the last year that have not been implemented by the agencies. Why do you think the agencies have resisted these recommendations?

Answer. The following six significant "cost saver" recommendations have not been implemented by the agencies:

- Limit Prospective Payment Services Reimbursement for Hospital Admissions Not Requiring an Overnight Stay
  CIN: A-05-89-00055
  Issued September 1989

  The OIG recommended that HCFA seek legislation to pay for covered services related to one-day admissions without an overnight stay as outpatient services at the lower of costs or charges. Current Medicare instructions provide that an admission occurs when there is an expectation that the patient will occupy a bed and remain overnight. This definition applies even if the person is later discharged or transferred to another hospital without actually using a hospital bed. Estimated savings over a five-year period total $590 million.

  HCFA's position is that payments for less than one-day stays are part of the overall reimbursement formula which is designed to average out the payments among all Medicare cases from outlier losses to short-stay profits. However, HCFA agrees that it may be appropriate to modify policy to encourage hospitals to treat cases involving observation after outpatient services as outpatient rather than inpatient cases.

- Develop Separate Dialysis Rates for Independent and Hospital Facilities
  CIN: A-01-87-00500
  Issued May 1989

  The Omnibus Budget Reconciliation Act of 1987 mandated a prospective payment system for outpatient dialysis treatments that differentiates between independent and hospital providers. HCFA sets the rates by combining independent and hospital facilities' costs. Adjustments are then made to the hospital rate to recognize their higher costs. However, corresponding downward adjustments are not made to the independents' rate to recognize their lower costs of providing services.

The OIG recommended that HCFA establish separate rates for independent and hospital dialysis facilities based upon their respective costs. Estimated five-year program savings from this recommendation total approximately $544 million. HCFA does not concur with this recommendation. They believe that implementing separate rates for independent and hospital dialysis facilities could increase Medicare expenditures and have an adverse effect on the quality of and access to care. HCFA contends that paying hospitals substantially more for a similar medical service does not foster competition nor does it reward efficiency. HCFA also cited the reluctance of Congress to lower payments for dialysis services because of potential adverse effects on quality.

o Recover Value Lost to the Trust Funds from Past Due Debts
OAI-03-88-00680
Issued May 1989

When an overpayment of Social Security benefits is detected, SSA requests repayment or offsets it against any current benefits. If eligibility for monthly benefits has ceased, however, and collection efforts prove to be unproductive, SSA terminates recovery actions. If the debtor becomes re-entitled to monthly benefits, the overpayment will be recovered from those payments.

An OIG inspection found that SSA will lose more than $470 million in interest to the trust funds by not having its outstanding debt of $94 million to invest until debtors become re-entitled to benefits. Moreover, the trust funds will lose over $1 billion in value during the next 20 years due to the addition of an estimated $625 million in delinquent debts from 1988 though 1997.

The OIG recommended that SSA institute a policy change to allow recovery of delinquent overpayments at the higher of the amount of interest income lost to the trust funds or the value lost to the trust funds due to inflation. SSA did not believe that it had the statutory authority to implement the OIG recommendation, but proposed to pursue a legislative initiative to allow use of the provisions of the Debt Collection Act against nonbeneficiary debtors.

o Income Tax Refund Offset
OAI-12-88-01290
Issued March 1989

The OIG determined that withholding income tax refunds due former overpaid Social Security beneficiaries could result in recovery of approximately $303.2 million over a five-year period, with most of the recovery occurring in the first two years.

SSA is in the process of resolving a number of systems, operational and legal issues associated with implementation of withholding income tax refunds. SSA cannot implement this recommendation administratively because legislative action is necessary. This legislative proposal is included in the President's FY 1991 budget.

- More Complete Employer Group Health Plan Information is Needed to Administer the Medicare Secondary Payer (MSP) Program
  CIN: A-09-89-00100
  Draft

  Despite HCFA's efforts to improve the collection of information on primary payer insurance of Medicare beneficiaries, more needs to be done. Accurate and timely information on other primary payers is needed to reduce annual Medicare overpayments estimated at up to $900 million which result from unidentified MSP cases.

  The OIG supports a legislative proposal drafted by HCFA which would require insurance companies, underwriters, and third party administrators to periodically submit Employer Group Health Plan coverage data directly to HCFA. HCFA's proposal was not included in the President's FY 1990 legislative program, and HCFA did not resubmit its proposal for inclusion in the Department's FY 1991 budget.

- Foster Care Administrative Costs
  OAI-05-87-00012
  Issued May 1987

  Our recommendation to limit the explosively growing Foster Care administrative costs still remains open. On January 23, 1990, we issued a management advisory report (AO-12-89-00001) which reviewed the findings and recommendations we have made pertaining to foster care administrative costs (includes the May 1987 report) and the status of management actions to date. Department officials concur with our recommendation to limit administrative costs and have in the past submitted the legislation to the Congress for consideration. To date, none of the proposals has been enacted. The President's FY 1991 budget also includes a proposal to cap the Title IV-E administrative costs. These costs have grown over 2,800 percent since 1981 to an estimated $882 million for FY 1991. In FY 1986 when we first recommended some type of limit for these costs, we estimated that as much as $147 million a year could be saved depending on what type of limitation was enacted.

  Currently, we are performing some additional work in the area of Title IV-E administrative costs. Research is underway on a comprehensive study of selected States to delineate the specific items and activities the States include in their claims for Title IV-E administrative costs. We anticipate preliminary results in eight to ten weeks.

WAR AGAINST DRUGS

Question. What role is your office playing in the war against drugs?

Answer. The OIG is contributing to the war against drugs by concentrating our efforts in two important areas, Medicaid and the Public Health Service, as detailed below.

Medicaid:

In 1988, $3.5 billion in prescription drugs were purchased by States for Medicaid patients. Based on Drug Enforcement Administration (DEA) data, an estimated 15 percent or $525 million of those purchases were for drugs subject to substance abuse (abusable drugs). These abusable drugs had a street value of about $7.5 billion.

We have developed a computer program that analyzes a State's Medicaid payment records, extracts transactions pertaining to DEA identified abusable drugs, and generates various data based profiles. These profiles identify the "heavy" prescribers (doctors), dispensers (pharmacies), and users (Medicaid beneficiaries) of abusable drugs. This information is then used as a basis for targeting investigative efforts into illegal drug activities.

Payment data analyzed in a Washington, D.C. pilot Medicaid audit revealed possible illicit activities by area physicians and pharmacies. The OIG is investigating these leads in cooperation with the FBI and DEA. At the request of the Governor of New Mexico, we conducted a similar analysis of that State's Medicaid drug payments over a two-year period. The results of our analysis have been provided to State authorities for further investigation. A similar analysis for the State of Maryland is underway.

We plan to inform the Governor of each State about the availability of our computer programs to assist in detecting potential drug abuse within the Medicaid program. Additionally, to assist their investigative efforts, the programs will be offered to State Medicaid program directors.

Public Health Service:

A PHS Audit Division was recently established within the OIG Office of Audit Services. This new Division has a number of audits and reviews pertaining to substance abuse scheduled in its FY 1990 - 1991 work plan. Three audits we will initiate during FY 1990 include the following:

- A review of the National Institute of Drug Abuse (NIDA) to determine whether NIDA resources are being adequately targeted to drug abuse research on treatment and prevention;
- An audit of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) to establish whether ADAMHA maintains a current inventory of the effectiveness and quality of the many drug treatment and prevention programs it sponsors; and
- An assessment of the cost and effectiveness of various substance abuse programs provided by ADAMHA.

Further, during FY 1991 we plan to survey the cost of alcohol/drug abuse treatment and prevention programs established under the Anti-Drug Abuse Acts, and evaluate the effectiveness of ADAMHA's treatment outreach efforts in reducing drug dependency.

In addition to these efforts, during FY 1990 OIG will complete a study of steroid abuse by youth. The study will explore such issues as:

- Who uses steroids?
- How and why are they used?
- What are the use patterns and influences?
- How are they distributed?
- What is the awareness of health risks?
- What is the awareness of health risks?

- What are possible drug testing procedures for athletes?
- What need is there for comprehensive education programs for students, parents, and coaches?

Our concerns with steroid abuse grew out of our investigations in illicit anabolic steroid activities, including illegal diversions from legitimate manufacturers, counterfeiting brand name steroid products, smuggling of steroids into the U.S., and illegal laboratories. These investigations resulted in over 25 arrests and convictions.

The following is an example of our investigations into steroid abuse:

After the steroid-related death of an Ohio high school athlete, which brought to public attention abuses in the sale and use of the drugs, OIG joined the Ohio State Pharmacy Board and the Ashtabula County Narcotics Agency in a series of investigations into the illicit sale of steroids. Dubbed "Project Bulk-Up," the joint effort has resulted in the convictions of four persons, with sentences of work release and fines. (File No. 5-88-00434-9, 5-89-00361-9, 5-87-00927-3)

POOR FINANCIAL MANAGEMENT

Question. GAO has called for government-wide improvements in financial management systems. There are reportedly billions of dollars of differences between balances recorded in accounting systems and financial reports.

What is your assessment of weaknesses in financial management of your agency?

Answer. The weaknesses in financial management at the Department of Health and Human Services can be directly attributed to the antiquated financial systems currently in place. These systems are labor-intensive, relying heavily on manual processing and report preparation. Also, they are not properly linked to one other (e.g., procurement and core accounting). These deficiencies have led directly to the reconciliation problems recently reported by GAO.

Question. What specific areas could be strengthened, and what is your plan for making improvements?

Answer. Improvement of financial management systems is a major HHS initiative. The Department is implementing the Phoenix Project, which is aimed at strengthening HHS financial management systems by:

- continuing to improve and standardize budget and financial information systems and processes for greater operating efficiencies and control;
- consolidating financial information into an agency-wide perspective as required by OMB Circular A-127;
- implementing the Standard General Ledger system in HHS;
- modernizing our automated financial management systems and those administrative management functions which provide data to Financial Management; and
- further improving compliance with OMB/GAO requirements and the Federal Managers' Financial Integrity Act.

The HHS plan addresses the need for the timely implementation of actions to address these priorities as they affect automated systems, whether wholly within the Phoenix structure (e.g., the Operating Divisions' Accounting System) or interfacing with it (e.g., the Personnel Payroll System).

The basic concept for the Phoenix Project derived from the Federal government's Reform '88 initiative, which sought to reduce inefficiencies in the operation of governmental administrative and financial systems, and to promote improved decision-making, accountability, and system integrity controls.

Question. Do you agree with GAO's assessment that managers need more and better training in Financial Integrity Act issues?

Answer. The Department agrees that training is a key element in implementing an effective FMFIA program. In this respect, the Chairman of the Council on Management Oversight has already requested HHS' Assistant Secretary for Personnel Administration to develop a comprehensive, Departmentwide FMFIA training program. In addition, the Director of the Department's FMFIA Program has been working with the Office for Civil Rights and the Family Support Administration in a separate effort to train their staffs under the auspices of the Office of Personnel Management.

HEAL PROGRAM SAVINGS

Question. You have estimated that savings of almost $75 million a year could be realized through curbing the growth of defaults in the Health Education Assistance Loan (HEAL) program.

What specific steps are you recommending to reduce the default rate in this program?

Answer. In addition to earlier OIG recommendations related to "due diligence" requirements which have been implemented by the Public Health Service (PHS), we have also made the following unimplemented recommendations.

- Limit the Federal guarantee to 80 percent of the loan (20 percent cost-sharing by the lender).
- Permit lenders to require co-signers.
- Eliminate the Federal responsibility for loan amounts which go into default because of death or disability, and allow lenders to impose a fee to protect themselves against such eventualities.
- Provide a uniform statute of limitations of 6 years for action by a lender against a defaulted borrower. This would encourage lenders to act more expeditiously in pursuing due diligence.

In addition to the above recommendations, we also made a number of recommendations involving enhanced revenues to SLIF (Student Loan Insurance Fund) which may have an indirect effect on the default rate. They include:

- Eliminate the current 8 percent ceiling on insurance premiums, charge insurance premiums over the life of the loans, and link insurance premium assessments to default rates in various health disciplines, schools, and lenders (e.g., the higher the default rate, the higher the insurance premium).

- Raise the insurance premium rate to an actuarially sound figure. Periodically adjust the premium rate to maintain the viability of SLIF.
- Make payments on delinquent loans as necessary to keep the would-be defaulted loans current, rather than waiting until they go into default and then paying the full amount of the defaulted loans plus interest.
- Sell "cured loans" (once in default and now in repayment status) to the secondary market, including "Sallie Mae".
- Seek authority to limit eligibility for HEAL assistance to U.S. citizens. The programs were not designed to underwrite the medical education of the entire world. The purpose of HEAL is to assist in the education of physicians for the American public. Foreign nationals coming to the U.S. for medical education are, by law, not permitted to remain here in order to become licensed and establish practice. Yet, many foreign students participate in the program and remain in the United States. Even worse for the program, those that return home have an extremely poor record of repayment and thus create a high default rate. There is no way these defaulted individuals can be made to pay.

Question. The Public Health Service has been unable so far to project future defaults. On what information did you base your prediction of annual savings of $75 million?

Answer. In November 1986, the OIG issued a report on the results of our Review of Selected Aspects of Program Administration of the Health Education Assistance Loan (HEAL) Program (ACN: 12-73276).

With respect to our estimate of annual savings of $75 million, we found that for the first 6 months of FY 1986, HEAL claims in dentistry, podiatry, and chiropractic medicine represented 70 percent of all defaulted HEAL claims paid by the SLIF. We concluded that obtaining statutory authority to link insurance premium rates to default rates in these three high-risk disciplines would result in premiums equalizing defaults. Total savings estimated in this area for FY 1988 were $74.7.

We also reported that despite actions taken by PHS in response to previous audit recommendations, claims for payment on defaulted loans were continuing to double each year. We reported that unless this growth could be controlled and reduced, we believed that an appropriation of $20.5 million would be needed during FY 1988 to pay claims after the previously self-sustaining loan insurance fund was exhausted.

Question. The Justice Department is charged with collecting on defaulted HEAL loans. What actions has the HHS IG taken to ensure that Justice is acting expeditiously on these cases?

Answer. Our reviews on collections of defaulted loans to date have concentrated on PHS performance in this area. Both our office and GAO previously reported that improvements are needed for more timely referrals of debts to DOJ. Corrective actions have been taken or are now being implemented by PHS.

PHS now requires that all accounts more than six months delinquent be referred to DOJ. Accounts are referred to DOJ when all other collection efforts have failed to result in collection of the debt. Other cases are referred to DOJ because of legal issues or a bona fide dispute of the facts exist. Finally, delinquent borrowers who have not responded to PHS dunning letters and have been properly notified are referred to a collection agency. Subsequently, uncollected accounts are referred to DOJ for litigation.

The HHS IG has not initiated any reviews or evaluations at DOJ to determine whether Justice is acting expeditiously on referred cases. We have determined, however, that PHS maintains a tracking system which shows that, as of February 9, 1990, PHS has referred cumulatively over 1,000 cases of uncollected loans totaling $33.1 million to DOJ. DOJ has obtained 350 judgments to date totaling $12.6 million, and has collected $2.1 million from HEAL debtors. We plan to meet with the DOJ Inspector General to discuss a review of this area by his office.

ADVISORY SERVICES

Question. Your budget calls for an $894,000 cut in advisory and assistance services. Exactly what are these services, and how would the proposed reduction impact the HHS IG's work?

Answer. The OIG has used advisory and assistance funding to supplement our staff with public accounting firms to conduct routine audits required by law or administrative requirement. These contract auditors allow our staff to concentrate on audits of a more complex nature, wherever the use of contract services would be inappropriate. Examples of contract audits are those devoted to reviews of administrative cost reports of Medicare intermediaries and carriers. Additionally, the amount of HHS dollars awarded to universities, State and local governments and other grantees has grown so large that it has become increasingly necessary to use contract auditors in testing whether grantees have used HHS funds properly and are in compliance with Federal procedures and policies.

The OIG has found that the prudent use of OIG resources yields a major return for every dollar invested in our staff, and far outweighs the return per dollar invested in contractor audits on routine matters.

In addition, we have determined there is a continuing need for highly specialized medical and other health professionals for a variety of technical services in support of our investigations, audits and inspections. Enforcement of new statutory authorities require the use of professionals to review cases regarding physician and hospital misconduct and substandard performances, as well as to conduct technical reviews of medical records. We could not employ full-time on the staff of the OIG expertise required because of the range of special knowledge needed and the requirement for peer review by specialists in active clinical practice.

With additional staffing we have received, and in order to support those payroll expenses, the OIG has opted to reduce funding for advisory and assistance services. Resources will be realigned from those previously devoted to monitoring of the catastrophic health insurance legislation.

SEPARATE SOCIAL SECURITY AGENCY

Question. Proposals have been made in the past to establish a separate Social Security Administration, and Congress will look at this idea again this year. What would be the impact on your workforce of a separate agency with its own Inspector General staff?

Answer. The HHS OIG currently has 1,400 FTE. Of this total, 200 - 300 FTEs would likely be transferred to an SSA independent of HHS. There would be little add-on costs with the transfer from HHS to an independent SSA, since most of the costs are already charged to the trust funds rather than through appropriations.

However, to provide for an effective OIG/SSA operation, an additional 200 - 300 FTEs would be needed in order to affect a minimum core of efficient operations. To have less than 600 FTEs for outlays of $250 million would make it virtually impossible to field a nationwide organization of eight payment centers and 64,599 employees distributed across 1,300 offices, and serving 39 million beneficiaries. Currently, the scale of operations at HHS absorbs most of the overhead and permits nationwide support.

The remaining OIG/HHS staff level would need to be brought back to a level of around 1,200 - 1,300 in order to return it to an efficient scale of operation for the remaining 250 or more programs. Although the remaining budget of HHS will be smaller than an independent SSA, the vast majority of the programs would remain with HHS. The complexity of these HHS programs and their special statutory audit and investigative requirements are far greater than for SSA. The restoration of a minimum scale for HHS would require adding FTEs at a rate of about 1 for 2 return ratio after the transfer.

IMPLEMENTATION OF INSPECTOR GENERAL RECOMMENDATIONS

Question. In December, Secretary Sullivan submitted the Department's first Report on Final Action, which describes management actions to recover disallowed costs and to assure effective use of funds based on findings of Inspector General reports.

How adequate is this report in tracking results in implementing Inspector General recommendations?

Answer. We are not fully satisfied that this will initially solve all the problems. However, the Department's Report on Final Action is a good first step. It will help ensure that disallowed costs are collected and reported fairly, and that management focuses on the implementation of OIG report recommendations which will result in a more effective use of funds. In developing this report, it became apparent that some of the systems used to record, track and report on follow-up needed to be strengthened. For example, the accounting system of the Office of the Secretary is receiving special attention to remove system weaknesses which were identified during the development of our first report. The Assistant Secretary for Management and Budget (ASMB) is working aggressively with the OIG to cure those deficiencies.

The OIG is modifying their automated management information system to include data on the implementation of recommendations and the collection of audit disallowances. This information will be used by the ASMB in carrying out his responsibilities as the Department's designated audit follow-up official. Additionally, the Department's annual audit follow-up plan now includes specific reports requested by the ASMB.

The Department is better equipped today to assess and report on OIG report recommendations, and subsequent reports to the Congress will reflect our commitment to continued improvement. Through personal meetings with the Department's Operating Division Heads, we are fostering a culture of commitment to make audit follow-up a new management priority.

RECOVERY OF SOCIAL SECURITY OVERPAYMENTS

Question. The OIG estimated the Social Security Administration could save over $1 billion in the next 20 years by allowing recovery of delinquent overpayments at the higher of the amount of interest income lost to the trust fund or the value lost to the trust fund due to inflation.

Could this be accomplished administratively by the SSA, or would legislation be required?

Answer. The OIG believes that SSA has the statutory authority to implement the OIG recommendation. In an opinion written in June 1988, the Office of General Counsel (OGC) stated that SSA clearly had common law authority to apply interest and penalty assessments as part of its debt collection procedures. Moreover, in a 1984 study, GAO indicated that the exclusion of SSA from the 1982 Debt Collection Act did not necessarily mean that SSA could not assess interest. Rather, the GAO felt that the Debt Collection Act did not prohibit SSA from charging interest under some other statute or principle of common law.

Question. What has been the reaction of the SSA and public interest groups to this idea?

Answer. SSA agrees that action should be taken, but maintains that there should be clear statutory authority to charge interest on overpayment amounts. SSA also disagrees with the savings potential identified in the OIG report, but does agree that savings of $560 million can be realized as the result of the OIG recommendation.

HARD SAVINGS

Question. Your latest semiannual report claims to have obtained over $5.6 billion in settlements, fines, restitutions, receivables and savings in fiscal 1989.

How much of this represents hard savings already realized, and what portion represents potential savings based on recommendations?

Answer. The $5.6 billion is composed of the following:

- o savings to programs resulting from legislative or regulatory actions or policy decisions of management on behalf of OIG recommendations;
- o amounts placed in accounts receivable for recoupment as a result of management determinations in favor of audit findings and recommendations; and
- o the amount of fines, savings, restitutions, settlements and recoveries determined through judicial or administrative processes in support of OIG investigative findings.

The policy of the OIG has been, and continues to be, to count only those recommendations with monetary consequences which have been implemented by the appropriate authority. Therefore, we claim only those audit disallowances which have been concurred to by the program managers and placed in the accounts receivable for collection. Similarly, fines, settlements and restitutions arising from OIG investigations are claimed only after final court settlement and collection orders are issued. Further, only after the Secretary has issued final regulations in the Federal Register do we report those OIG recommendations which will create savings as a result of regulatory correction. We then use the monetary estimates established by the program management, not by the OIG. We do so not because we think program officials have better data than OIG, but because their numbers are neutral to the OIG and not under our control; therefore, such numbers are more credible.

Finally, much of our savings arise from legislative action on behalf of our recommendations. We claim those savings only after enactment into law. We then use the Congressional Budget Office (CBO) scoring of the savings, not our own estimates. Once again, we do this not because we believe CBO has better data than OIG, but because it is derived independently of the OIG and is therefore more credible. Examples of savings resulting from legislative changes are illustrated in the following summary of OIG recommendations contained in OBRA 1989.

OBRA 1989 SAVINGS BASED ON OIG RECOMMENDATIONS *
($ in millions)

I. MEDICARE	
Reduction in Capital Costs for Inpatient Services ACN: 14-52083; ACN: 09-52032; ACN: 09-52002; ACN: 09-52020	$580
Reductions in Certain Overpriced Procedures (Cataract and CABG only) OAI-02-89-00050; CIN: A-0788-00080	$940
Reductions in Payments for Anesthesia Services OAI-02-89-00050; CIN: A-07-88-00080	$245
Reduction in Capital Payments for Outpatient Hospital Services ACN: 14-52083; ACN: 09-52032; ACN: 09-52002; ACN: 09-52020	$23
Clinical Diagnostic Lab Tests OAI-02-89-01910	$770
Durable Medical Equipment OAI-02-88-00100; CIN: A-05-87-0013; OAI-02-88-00060; OAI-04-87-00017; CIN: A-04-87-02000	$690
Medicare as Secondary Payer CIN: A-10-86-62016; CIN: A-09-89-00100	$2,315
Payment for ESRD Services CIN: A-09-87-00108	$540
Extend Part B Premium MAR 6/85	$2,355
Total savings based on OIG recommendations	$8,458
GRAND TOTAL, OBRA 1989 MEDICARE SAVINGS	$10,241
OIG PERCENTAGE OF OBRA SAVINGS	**83%**
II. SOCIAL SECURITY	
Acceleration of Deposits (OIG est.) (Revenue Enhancement Section of OBRA) CIN: A-09-89-00075	$15,000

* CBO 5-year estimates

Question. How much of these recommended savings are repeats of proposals made in prior years, but never implemented?

Answer. None. All savings claimed in the 1989 HHS OIG Semiannual Reports represent new actions. Savings are not claimed until the recommendations on which they are based are implemented.

We have more than $27 billion in potential annual savings in the OIG Cost Saver Handbook (the so-called Red Book) which have never been claimed. Much of which may never be claimed because they have not been implemented. We are submitting for the record our last edition of the Red book which is currently undergoing revision. We will furnish to the committee the revised version as soon as it is completed.

The OIG semiannual report has separate appendices to distinguish those savings effected during the reporting period from those savings which would be realized if favorable action were taken on OIG recommendations.

Question. Is it fair for you to claim $12.1 billion in savings over 5 years by simply speeding up social security payroll tax deposits, which shifts payments to earlier years?

Answer. In our April 1 - September 30, 1989 Semiannual Report to the Congress, we estimated that $15.5 billion in monetary benefits could result from our proposal to accelerate payroll tax deposits for large employers. The $15.5 billion consists of $12.1 billion in tax collections being shifted to earlier years and $3.4 billion in earned interest. The estimated monetary benefits from this unimplemented proposal are composed of general fund revenue (withheld income tax deposits) as well as Social Security trust funds revenues (Federal Insurance Contributions Act [FICA] deposits). Our Management Advisory Report (A-09-89-00075) treats the $15.5 billion as a deficit reduction opportunity consisting of the $12.1 billion being shifted to earlier years and the $3.4 billion in interest that would be earned from the accelerated deposits.

Our proposal was based on the existing Department of the Treasury definition of a large employer: one whose total payroll taxes (income tax and FICA withholdings) exceed $3,000 for each pay period. Congress partially implemented our recommendation with the passage of the OBRA 1989, which requires large employers to deposit payroll taxes by the next banking day after the date that a payroll is distributed. However, the Act also redefined a large employer as one whose total payroll taxes exceed $100,000 for each pay period. The CBO estimate for implementation of this provision reduces the expected monetary benefits from $15.5 billion to $3.1 billion (including shifting and interest earned) over the five-year budget cycle beginning in FY 1990. The CBO amount ($3.1 billion) will be shown in our October 1, 1989 - March 31, 1990 Semiannual Report to the Congress as the amount of monetary benefits associated with implementation of our proposal.

MEDICARE AS SECONDARY PAYOR

Question. You issued a draft report in September 1989 concluding that the Medicare program is annually paying $400 to $900 million that actually should be paid by other primary insurers. In November 1989, Congress enacted reforms as part of reconciliation legislation that CBO estimates should save $300 million in fiscal 1990 by strengthening the Medicare Secondary Payor program.

What is your assessment of how effective the new legislation enacted by the Congress will be in reducing Medicare payments that should be paid by private insurance?

Answer. The OIG's Office of Audit Services has developed a data base using SSA/HCFA computer interfaces to identify Medicare secondary payer (MSP) situations. This data base is virtually identical to the Internal Revenue Service (IRS)/SSA/HCFA data match initiative mandated by OBRA 1989. Its development has greatly assisted both HCFA and SSA in implementing the OBRA 1989 data match initiative.

We support the MSP provisions contained in OBRA 1989 and believe that these changes will be effective in reducing MSP overpayments. However, we believe that the magnitude of the program losses as a result of inappropriate Medicare payments and the complexity of the MSP program will require a number of distinct actions to rectify current deficiencies. Even after implementation of the OBRA 1989 provisions, MSP overpayments will undoubtedly still occur to some extent.

We continue to support the Department's unenacted MSP legislative proposal, which would require insurers, underwriters, and third-party administrators of employer group health plans to notify HCFA about covered individuals who are enrolled in insurance programs to which Medicare is secondary payer.

The Department's unenacted legislative proposal and MSP provisions contained in OBRA 1989 both address prevention of MSP overpayments through increased identification of primary payers. We have also put forth a proposal aimed at recouping MSP overpayments which have already occurred. We recommended in a report entitled *Medicare as Secondary Payer -- A Restitution Proposal* (AO-12-89-00002) that the Department seek legislation to establish a voluntary disclosure and recovery program which would permit insurers, employers or third-party administrators to identify improper MSP payments and make restitution. Any insurer not participating in the program would be subject to treble damages, plus costs, with respect to each such claim subsequently identified by the Federal government. Non-participating insurers would also be subject to debarment for three years from all Federal government contracting programs if the government later identifies improperly processed MSP claims. We believe that the implementation of this program will facilitate the identification and recoupment of overpayments which have already occurred.

Question. Do you think the President's fiscal 1991 Medicare contractor budget is sufficient to adequately carry out these new initiatives, as well as payment safeguard activities in general?

Answer. The FY 1991 budget request of $334.8 million for Medicare payment safeguard activities is comprised of the following:

		Million	Increase/ Decrease
o	Medical/Utilization Review	$146.7	$1.7
o	Provider Audit	135.7	4.3
o	Medicare Secondary Payer	52.4	-3.3
	Total	$334.8	$2.7

The OIG defers to HCFA on the adequacy of funding levels for payment safeguard activities. HCFA believes the $334.8 million budget request is adequate for maintenance of on-going contractor activities. HCFA has requested a $36.5 million contingency to implement the OBRA 1989 MSP provisions and $8.9 million will be needed to implement the OBRA 1989 IRS/SSA/HCFA data match initiative in FY 1992.

OVERPRICED MEDICARE LAB PAYMENTS

Question. In a report on Medicare lab payments, the Inspector General's Office found that Medicare, on average, paid nearly twice the price charged to physicians (p.33 of April - September 1989 semiannual report).

How much do you estimate would be saved if Medicare lab payments were held down to the price charged physicians?

Answer. In January 1990, the OIG issued a report entitled Changes are Needed in the Way Medicare Pays for Clinical Laboratory Tests, which compared prices charged to Medicare and physicians by large commercial laboratories. Based on our analysis, limiting independent laboratories to the prices charged physicians would save about $420 million per year. Limiting physicians and hospitals to the same prices would save about $850 million and $560 million, respectively. Thus, the total potential savings is approximately $1.8 billion a year, or nearly one-half of current outlays.

Question. Would you favor demonstration projects to test competitive bidding on Medicare lab services?

Answer. The OIG strongly supports the use of such demonstration projects based on our analysis of Medicare expenditures for lab services. We issued a report in January 1990 entitled Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests, which found a large discrepancy in prices paid by Medicare and physicians for laboratory services. With Medicare Part B laboratory outlays approaching $4 billion annually, volume purchasing offers the potential for very significant savings.

Question. What can the Health Care Financing Administration do, under current law, to reduce excessive lab fees under Medicare?

Answer. In January 1990, we issued a report entitled Changes Are Needed In The Way Medicare Pays for Clinical Laboratory Tests, which showed that the most dramatic differences between Medicare and physician prices were on test packages, or profiles. In response to our report, HCFA is conducting a survey of available test packages with a view toward establishing national payment caps for these types of tests. Current law does not appear to preclude such payment limitations. However, we did recommend that the law be revised to permit Medicare reimbursement to labs at the market price levels, as reflected by laboratory charges to physicians.

HEALTH CARE FINANCING ADMINISTRATION

STATEMENT OF GAIL R. WILENSKY, ADMINISTRATOR

ACCOMPANIED BY:

LEE MOSEDALE, ACTING DIRECTOR, OFFICE OF BUDGET AND ADMINISTRATION

ELIZABETH CUSICK, OFFICE OF THE ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET, DHHS

PREPARED STATEMENT

Senator HARKIN. The subcommittee will now hear testimony from the Health Care Financing Administration and the Social Security Administration.

From HCFA we have Dr. Gail Wilensky, Administrator, accompanied by Mr. Mosedale—did I pronounce that right?— Acting Director of the Office of Budget and Administration for HCFA.

Dr. Wilensky, welcome to the subcommittee. Your statement will be made a part of the record in its entirety. And if you could highlight it, I would sure appreciate it. Thank you.

[The statement follows:]

STATEMENT OF GAIL R. WILENSKY

Mr. Chairman and Members of the Subcommittee, I am pleased to present to you today the Fiscal Year 1991 budget request of the Health Care Financing Administration.

As I begin my appointment as Administrator of HCFA, I am mindful of the many tasks before us. The past year has been one of both change and continuity for the agency. Significant changes in the Medicare and Medicaid programs have resulted from such major legislation as the Medicare Catastrophic Repeal Act and the Omnibus Budget Reconciliation Act of 1989. At the same time, the unabated growth in national health care costs continues to pose serious, unresolved challenges to the Congress and to the Administration in our concerted efforts to constrain expenditures while ensuring quality of care.

The FY 1991 HCFA request outlines our agency-wide proposals to help meet these challenges through more effective and efficient management of Medicare and Medicaid. These initiatives include the introduction of new approaches to our programmatic responsibilities, as well as refinements of present administrative practices.

In our primary program management proposal, we seek to consolidate all Medicare and Medicaid State Certification activities in a new Survey and Certification Revolving Fund, and to make this account self-sustaining through the assessment and collection of user fees. This proposal is a logical extension of the laboratory inspection funding mechanism mandated by the Congress in the Clinical Laboratory Improvement Amendments of 1988. It is an effort to equitably assign costs to those parties who most benefit from participation in the Medicare and Medicaid programs. This policy has only a modest effect on the Federal deficit, as Medicare and Medicaid will continue to pay their fair share for these important activities.

Our request also puts forth a number of proposals to slow the escalation of Medicare benefit outlays and to enhance the roles of Medicare and Medicaid in the managed care arena. Under current law and without Catastrophic Health Insurance, Medicare benefits are expected to grow by approximately 10 percent in FY 1991. Our proposals would hold this rate of growth to less than 5 percent, for a total savings of $5.5 billion.

At this time, I would like to briefly discuss each of the respective accounts under the purview of this

Subcommittee: Grants to States for Medicaid, Payments to the Health Care Trust Funds, Program Management, and the proposed Survey and Certification Revolving Fund.

GRANTS TO STATES FOR MEDICAID

During FY 1991, Medicaid is expected to serve more than 26 million recipients, an increase of approximately 4 percent over the previous year. Under current law, we request a total of $45 billion for the Federal share of Medicaid benefits and administrative costs. This is an increase of $4.8 billion, or nearly 12 percent, over FY 1990. Much of this increase is due to the impact of recent legislation and to the steeply rising costs of institutional services.

The Administration is proposing a package of Medicaid managed care initiatives that will better integrate services, help to control unnecessary utilization, and improve both access to and quality of care. These enhancements are expected to cost $25 million.

As part of our survey and certification proposal, we propose to transfer all Medicaid State Certification responsibilities to the new Revolving Fund. This would reduce the Grants to States for Medicaid appropriation by more than $113 million in FY 1991.

PAYMENTS TO THE HEALTH CARE TRUST FUNDS

The Payments to the Health Care Trust Funds account incorporates several distinct Federal contributions to the Medicare Trust Funds. By far the largest of these is the Federal general revenue subsidy of Supplementary Medical Insurance. This subsidy currently finances more than 75 percent of Part B expenditures. Because of the substantial Part B savings which would be realized through passage of the Administration's legislative proposals, our proposed law request of $35.1 billion is $2 billion less than under current law.

PROGRAM MANAGEMENT

The Program Management request encompasses three integral agency activities: Research, Medicare Contractors, and Administrative Costs. It anticipates that all State Certification activities and related administrative support presently included in the Program Management account will be transferred to the new Revolving Fund.

Our request is $1.9 billion, comprised of $1.8 billion to be transferred from the Medicare Trust Funds and $90.1 million to be appropriated from Federal general funds. This is $41.4 million less than our FY 1990 appropriation, a reduction attributable to Catastrophic repeal and the transfer of survey and certification responsibilities to the Revolving Fund.

I would now like to briefly highlight each activity of the Program Management account.

Research

Our request for Research activities is $36 million, $3.8 million more than the comparable FY 1990 appropriated level. As we intend to use the $17.8 million FY 1990 Rural Health Care Transition Grant appropriation in FY 1991 as well as in FY 1990, no such grant monies are requested for FY 1991.

Our Research program will continue to concentrate on high-priority issues crucial to the agency mission. We propose to devote $6.0 million to studies of physician and ambulatory care payment systems, and $7.0 million to quality of care research. $16.2 million (or 45 percent) of the total request is required to fund projects mandated by Congressional legislation, including $5 million to carry on projects stipulated by OBRA 89.

Medicare Contractors

The Medicare Contractors request seeks funding for the operating costs of the private organizations that process claims, conduct Payment Safeguard activities, and provide program information to beneficiaries and providers. Our request is $1.58 billion, an increase of $129 million (or almost 9 percent) over the FY 1990 appropriated level. This includes a contingency reserve of $100 million, and $73 million earmarked for OBRA 89 activities.

The responsibilities of the contractors are the core of the Medicare program, and therefore HCFA's quest to improve the management of Medicare must in large part be focused here. We request moderate increases over FY 1990 appropriated levels in each of the primary Contractor functions. Our request for an increase in Payment Safeguards activities is particularly notable, for it recognizes the significant trust fund savings produced by these investments. Payment Safeguards include provider audits, contractor medical and utilization reviews, and the Medicare Secondary Payer program, which identifies situations where other insurers have primary payment responsibility.

Among the other highlights of the Contractors request is the full operation and planned enhancement of the Common Working File, an automated system which vastly improves claims processing operations through the institution of regional Medicare computer databases. In this and other initiatives such as shared systems maintenance and processing, our Contractors request vigorously pursues the promise which well-designed electronic data systems can offer.

Administrative Costs

The Administrative Costs activity of the Program Management account provides for the operating expenses of the Health Care Financing Administration. Our request of $285.3 million is $39.7 million (or 12 percent) less than the FY 1990 appropriated level. Similarly, our full-time equivalent (FTE) request of 3,577 is 440 positions under the FY 1990 level of 4,017. These reductions in funding and staffing reflect the effects of Catastrophic repeal, and the transfer of 380 Medicare and Medicaid Survey and Certification personnel to the new Revolving Fund account.

Included in the Administrative Costs request are two management initiatives of special note. The first is the Project to Redesign Information Systems Management (or PRISM), which constitutes the agency's comprehensive effort to upgrade its internal information systems. The other is a Medicare survey, still in the developmental stages, through which we will gather feedback from beneficiaries about the nature and costs of services, out-of-pocket expenses, and the overlaps of Medicare with other coverage. This on-going survey will provide the timely, detailed information required by the Congress, and necessary to enlightened Medicare policy analysis and policy-making.

SURVEY AND CERTIFICATION REVOLVING FUND

The proposed Survey and Certification Revolving Fund consolidates in a single account the various facility survey functions of the Medicare and Medicaid programs, along with the new schedule of inspections required by the Clinical Laboratory Improvement Amendments of 1988.

In essence, the total costs associated with direct surveys as well as corresponding Federal administrative expenses would be funded through user fees to be collected from all providers and suppliers. The entire survey and certification program would be self-financed, and would not require any appropriated budget authority in FY 1991 or in any subsequent year. User fee collections would totally offset the proposed $510.1 million in operating expenses, including the costs of the proposed 550 FTE staffing level.

CONCLUSION

Our FY 1991 budget request is the product of a coordinated Administration effort to improve the management of the Medicare and Medicaid programs, which together will serve the health care needs of more than 57 million Americans in FY 1991. This effort brings together concerns of cost, quality, and equity. We are confident that our request successfully addresses all of these concerns while expanding the agency's role in Federal deficit reduction.

I would be happy to respond to any questions that you may have.

OVERVIEW OF FISCAL YEAR 1991 REQUEST

Dr. WILENSKY. I am, as you have indicated, the newly confirmed administrator of the Health Care Financing Administration. And I am pleased to present to you today the fiscal year 1991 HCFA budget request. I would like to just briefly summarize this statement, as you have indicated that my full statement will be submitted for the record.

I am mindful as I begin my appointment at HCFA of the many tasks before us. The Congress and the administration face serious, continuing challenges in terms of constraining expenditures while ensuring quality of care in the Medicare and Medicaid Programs.

Our 1991 budget request outlines agencywide proposals to help meet these challenges through more effective and efficient management of Medicare and Medicaid. These initiatives include both refinements of past practices and the introduction of new administrative approaches.

In our primary program management proposal, we seek to consolidate all Medicare and Medicaid State certification activities in a new survey and certification revolving fund and to make this account self-sustaining through the assessment and collection of user fees.

This policy has only a modest effect on the Federal deficit, as Medicare and Medicaid will continue to pay their fair share for these important activities. It is a logical and equitable extension of the laboratory inspection funding mechanism created by Congress in CLIA 88.

Our request also puts forth a number of proposals to slow the escalation of Medicare benefit outlays and to enhance the roles of Medicare and Medicaid in the managed care area. Under current law and without catastrophic health insurance Medicare benefits are expected to grow by about 10 percent in 1991. Our proposals would hold this rate of growth to less than 5 percent, for a total savings of $5.5 billion.

With regard to grants to States for Medicaid, under current law we request a total of $45 billion for the Federal share of Medicaid benefits and administrative costs. This is an increase of nearly 12 percent over the 1990 appropriation. This increase is due primarily to the impact of recent legislation and the steeply rising costs of institutional services.

The administration is proposing a package of Medicaid managed care initiatives that will help to integrate services, control unnecessary utilization, and improve both access, and quality of care. These enhancements are expected to cost about $25 million.

As part of our survey and certification proposal, we propose to transfer all Medicaid State certification responsibilities to the new revolving fund. This would reduce the Medicaid appropriation by about $113 million.

In the payments to the health care trust funds account, our proposed law request of $35.1 billion is $2 billion less than under current law. This proposed law request reflects the substantial part B savings which would be realized through the enactment of the administration's legislative package.

Our program management request is $1.9 billion. It encompasses three integral agency activities: Research, Medicare contractors, and administrative cost. This request is $41 million less than our 1990 appropriation, a reduction that is attributable to the repeal of catastrophic and the transfer of State certification activities to the proposed revolving fund.

Our request for research activities is $36 million. Through this request we look to continue our research emphasis on such high-priority areas as physician and ambulatory care payment systems and quality of care.

Our Medicare contractors request is $1.6 billion, including a contingency reserve of $100 million and $73 million earmarked for OBRA 1989 activities. This is an increase of 9 percent over the 1990 appropriation. It includes increases in each of the primary contractor functions, that is, claims processing, payment safeguards, and productivity investments. Our request for increased payment safeguards activities is particularly notable, for it recognizes the significant trust fund savings produced by these investments.

The administrative cost activity of the program management account provides for the operating expenses of HCFA. Our request of $285 million is 12 percent less than the 1990 appropriated level. Similarly, our FTE request of 3,577 is 440 positions under the 1990 level. These reductions in funding and staffing reflect the effects of catastrophic repeal and the transfer of 380 Medicare and Medicaid State certification personnel to the new revolving fund account.

The proposed survey and certification revolving fund consolidates in a single account the various survey functions of the Medicare and Medicaid programs, along with the new schedule of lab inspections required by CLIA 88.

In essence, all direct survey costs as well as corresponding Federal administrative expenses would be funded through user fees to be collected from all providers and suppliers. The entire program would be self-financing, and would not require any appropriated budget authority in 1991 or in any subsequent fiscal year. User fee collections would totally offset the proposed $510 million in revolving fund operating expenses, including the costs of 550 FTE's.

In conclusion, our budget request is the product of a coordinated administration effort to improve the management of the Medicare and Medicaid Programs, which together will serve the health care needs of more than 57 million Americans in 1991. This effort brings together concerns of equity, cost, and quality. We are confident that our request successfully addresses all of these concerns.

I would be happy to respond to any questions that you may have.

VARIATION IN MEDICARE PHYSICIAN PAYMENTS

Senator **Harkin**. Thank you very much. I have been hearing from a number of physicians from around the country about disparities in HCFA reimbursement payments for some procedures based upon geographical locations. This just does not seem to make sense, where the same procedure, for example, in Los Angeles is reimbursed at three to four times what it is in Des Moines, IA.

And, yet, doctors have told me that they have verified this with some friends in other regions. The rent—in this one area—was cheaper in Los Angeles than it was in Des Moines. All the other costs seemed to be either the same or cheaper, and yet they were reimbursed at a higher rate because of a geographical difference.

Is anything being done to avoid perpetuating unfair geographic disparities in fees for certain services?

Dr. **Wilensky**. As you know, under our current payment systems, payments have been based on an historical basis of charges by physicians.

Senator **Harkin**. Based on 1971, or is it 1972?

Dr. **Wilensky**. It is based on 1973.

Senator **Harkin**. On 1973.

Dr. **Wilensky**. On 1973. As you also are aware, a physician payment reform package was recently enacted which is scheduled to go into effect in fiscal year 1992. It provides for a national fee schedule. And one of its major purposes is to get away from historical differences that do not reflect true costs, that have been perpetuated either because of differences in specialties, or because of differences in geographic location.

Senator **Harkin**. Excuse me, this is the relative values scale that you are talking about?

Dr. **Wilensky**. Right.

Senator **Harkin**. So, there will not be any geographical costs built on to that?

Dr. **Wilensky**. There is a geographical cost index that is applied. It is based on practice costs in the geographical area as measured. And under our estimates, in the case that you raised, for example, physicians in Iowa would in fact do considerably better under the new system than they do under the existing system. We now actually try to go out and measure true practice costs.

Senator **Harkin**. The relative value scale is going to shift more of our resources towards primary care?

Dr. **Wilensky**. And also reduce the differential between urban and rural areas.

Senator HARKIN. But also I am talking about the geographic differences, say, in one radiology test performed in Iowa as compared to California.

Dr. WILENSKY. The new fee schedule is based on several factors. It is based on the time and effort involved in doing the procedure. That is the relative value part. There also is a geographic practice cost index, which will reduce the disparities that have existed historically. This is an attempt to include a factor that is based on actual practice cost differences and to reduce exactly the sort of ingenuity that you mentioned in your example: the Iowa versus California disparity in payments for a specific service.

Senator HARKIN. So you are scuttling the 1973 base?

Dr. WILENSKY. Yes.

Senator HARKIN. And going to a new base based upon——

Dr. WILENSKY. Estimated values, calculated values.

Senator HARKIN. Right now?

Dr. WILENSKY. Right. The new fee schedule is an attempt to get away from historical charges that became built into the system.

Senator HARKIN. What is the timeframe for implementing the relative value-based scale?

Dr. WILENSKY. Certain physician payment methodologies that are consistent with the relative value scale will be implemented in fiscal year 1991. But the actual relative value scale itself begins to be implemented in fiscal year 1992. It is a phased-in strategy.

COMPETITIVE BIDDING

Senator HARKIN. Last year I brought up the point about competitive bidding for medical equipment, such as oxygen bottles, which in the general marketplace cost about $100, yet the contracts allow for much more. What plans do you have to allow competitive bidding for durable medical equipment?

Dr. WILENSKY. It is my understanding that there was a congressional moratorium placed on the implementation of bidding demonstrations through December 31, 1989. We are now giving some serious consideration to conducting competitive bidding demonstrations. Previous to the moratorium, we at HCFA had been in the process of trying to do this. Some design work was conducted in the mid-1980's. But soon thereafter, Congress enacted legislation that placed a moratorium on such activities.

Some of this work, because it is now several years out of date, will have to be revisited to make sure the design is still relevant. But we are giving this matter consideration.

Senator HARKIN. As I understand it the moratorium has been lifted. It was not our intention for you to go out and have a demonstration program, but to actually go out and implement competitive bidding. Is there some reason why you should not just go right ahead and implement competitive bidding for durable medical equipment? And also for these lab tests too?

Mr. MOSEDALE. I think there are tremendous considerations in entering into a program like this. We certainly do not want to create more perturbations than are already there. There are certainly big problems in the lab area, as you pointed out in your chart. We want to make sure that we do not make the situation even worse by implementing something immediately. In other words, would there be areas, labs in rural areas, for example, that could not compete with large urban labs? Would we wind up not having lab services available in those particular areas?

We want to make sure that there is enough lab capacity out there. That is one of our big considerations.

Senator **Harkin**. And I suppose response time is also a consideration?

Mr. **Mosedale**. Yes; it is.

Senator **Harkin**. In lab tests?

Dr. **Wilensky**. HCFA in general has a lot of interest in the competitive bidding issue, and we will be glad to revisit it.

PROPOSED HOSPITAL CUTS

Senator **Harkin**. Once again, you are targeting hospitals to achieve the bulk of the savings, about $4.1 billion. Yet I have met with my hospitals from Iowa, and the data indicates that hospital expenditures have remained virtually constant as a percent of GNP since 1982, and many hospitals appear to be barely surviving due in part to past cuts in part A Medicare reimbursements.

Why do you continue to target hospitals to achieve the deficit reduction, when Medicare outlays for physician services are rising much faster than hospital benefits?

Dr. **Wilensky**. As you know, we are proposing reductions in both areas. We are proposing that there be a reduction in the hospital area, and that there be reduction in the part B physician area. So, the inclusion of reductions in part B, which has been growing very rapidly, is still clearly a matter of some concern to us, and we are trying to proceed with such reductions.

Nonetheless, there are areas in part A in which we believe there are further savings that can be achieved. In particular, we have been concerned about the level of hospital capital expenditures. As you know, capital expenditures are not part of the prospective payment system. They are paid on a passthrough basis. And they have, not surprisingly, been growing at a substantially faster rate than hospital expenditures in general.

We are proposing a differential reduction in terms of capital expenditures: a lower reduction for rural hospitals and a higher reduction for urban hospitals. We also believe that there are still some savings that can be achieved in the hospital area, but agree that there has been a substantial moderation in the rate of increase. And our concern of late has been that we are careful to have protection for hospitals that may be at some risk. We have taken measures to try to make sure that while on average hospitals are doing OK, there is some protection provided to certain kinds of hospitals that may be more vulnerable than others.

Mr. **Mosedale**. Mr. Chairman, I think it is also important to point out that for this year, for the first time, we are trying to make the savings proposals consistent with the relative level of benefit payments for hospitals and for physicians. In other words, about 60 percent of the dollar amount of cuts will be coming from part A and 40 percent from physicians and other part B services. This corresponds to the relative levels of part A and part B benefit payments. So, we are trying to keep cuts proportionate to expenditures.

RURAL HEALTH CARE TRANSITION GRANTS

Senator HARKIN. I understand. I asked the Secretary this morning this question and I wanted to ask you also. What is your rationale for not requesting funds to continue the rural hospital transition grant program?

Dr. WILENSKY. Our reason is that the 2-year program has been extended to a third year. We would like to be able to evaluate the impact of that program before we propose a continuation. It is simply that we do not believe at this time, because of the short amount of time that it has been in effect, that we are able to say what the effects of the grant program are. We would like to be able to do that first.

Senator HARKIN. You could not keep it going another year while you look at the results?

Dr. WILENSKY. We will be keeping it going, but we think it is now time to try to understand the impact of the program.

Senator HARKIN. What plans do you have to do the study? Have you got something already under way? And, if so, well, when can we see this completion?

Dr. WILENSKY. HCFA is conducting an evaluation of the impact and effectiveness of this program on rural hospitals, and we expect that the results of this evaluation will in fact be available this year.

Senator HARKIN. This fiscal year?

Dr. WILENSKY. This fiscal year.

Senator HARKIN. I assume that you would make that information available to us as soon as you have it completed?

Dr. WILENSKY. Yes.

Senator HARKIN. In other words, it is early. I would like to see it as soon as it is completed, rather than waiting until the end of the year.

Dr. WILENSKY. Right.

MEDICARE REIMBURSEMENT FOR WHEELCHAIRS

Senator HARKIN. I have heard from a number of disabled individuals regarding Medicare reimbursement for wheelchairs. Evidently the Budget Reconciliation Act of 1987 placed wheelchairs under a category which only allowed for 15 months rental and no purchase. Vendors are then required to continue to provide the chairs to an individual for life with no reimbursement beyond the rent from the first 15 month period. Thus, vendors are reluctant to enter into agreements with people who have long-term needs, even though Medicare had in fact paid the equivalent of 150 percent of the submitted purchase price by the end of the 15 months.

So, they cannot purchase a wheelchair. An attempt was made to correct this situation last year. But it seems that what we did is create a separate category for motor driven wheelchairs that would allow purchase of those chairs by people with chronic disabilities, we did not include the nonmotorized wheelchairs under the same category.

It does not seem to make sense to deny people the opportunity to purchase what they call push chairs. Now, again, is this something you change administratively?

Dr. **Wilensky**. No; it is not. It was part of the OBRA provision. As you may know, prior to that legislation, the decision of whether to pay on a rental basis or a purchase basis was based on economics. The anticipated length of use and costs were examined, and the most economical choice was funded. That changed as of OBRA 1987.

Senator **Harkin**. See, what has happened, as I understand the situation, is a vendor will not rent a wheelchair under Medicare because while they get paid for 15 months, at the end of 15 months, they don't get paid any more, but they have got to maintain that chair for the length of the individual's life.

Dr. **Wilensky**. My understanding is that the organizations which represent the durable medical equipment suppliers supported the OBRA 1987 provision that limited charges to rental charges only. So I agree with the issue that you are raising. It is not an administrative issue. The issue arises from the statute that does not allow continuance of decisionmaking on the basis of economics.

Senator **Harkin**. Right now, they can purchase the motorized chair, but not the push chair. Would you support that change to allow them to purchase a push chair?

Mr. **Mosedale**. I think we have to be very cautious about this, because there is tremendous opportunity for abuse. I think that is one of our primary concerns. The sale of wheelchairs was tremendous before this initial cap was put in place. We are concerned about the potential ramifications of going back to the old method, where there was a tremendous number of wheelchairs that were sold that may not actually have been necessary. So, we are concerned about that.

Dr. **Wilensky**. I think that if we were to change, we would want to be sure that there were appropriate safeguards put into place, so that you do not have the potential for abuse.

Senator **Harkin**. That is right, I understand.

Dr. **Wilensky**. And that is our only concern.

Senator **Harkin**. Well, if we tighten down and made sure that they were only being purchased by people who had long-term needs.

Dr. **Wilensky**. I believe that is correct.

REPAIR OF WHEELCHAIRS UNDER MEDICARE

Senator **Harkin**. Repairs too are a problem. While the chair is being rented, repairs must be done by the vendor, which is pretty hard for someone who is in Iowa when the vendor is in Chicago. If the chair breaks down, they have got to pay for the repair themselves.

Dr. **Wilensky**. The reimbursement to the supplier of the wheelchair includes a maintenance provision. And what is supposed to happen is that the supplier who rents the equipment is to reimburse the entity that actually performs the maintenance. Were HCFA to pay for an out-of-town repair separately, we would then be paying for maintenance twice. Maintenance is included in the rental amount that is provided to the supplier.

So, it is not correct as is sometimes assumed that HCFA does not pay, or Medicare does not pay, for repairs that are performed out of town.

Senator HARKIN. Do you support just taking the maintenance provision out of the rental agreement? I mean, why do they not just rent it, and let them get it repaired wherever they want to get it repaired.

Repair provisions in rental agreements are sometimes not in the renters' best interest. Perhaps if they shopped around a little bit, they might find a better provision for repairs.

Dr. WILENSKY. It is our belief that in general this procedure has been working well. We do recognize that particularly in emergency situations on-out-of town visits that there can be some complications. And we do believe that the out-of-town agency ought to be reimbursed for their expenses. Maintenance is included in the regular supplier's rental price.

It is our opinion, again, that in general this process has been working reasonably well.

Senator HARKIN. It is interesting to know because, it has been my experience that wheelchairs do not break down all that often. And if everyone who has one is paying this provision, they are paying for maintenance, and they are not getting maintenance. I wonder about the cost effectiveness of it. This is something you might take a look at.

Dr. WILENSKY. OK.

Senator HARKIN. More and more people are getting wheelchairs and becoming more and more mobile. They are just not sitting in one place, and they may need to get maintenance in some other area.

I may have some more followup questions on that.

Dr. WILENSKY. Fine.

PAYMENT SAFEGUARDS

Senator HARKIN. Let me just cover one other area here: payment safeguards. Last year's hearings convincingly showed that the payment safeguard activities—including prepayment claims reviews and postpayment audits—saved the taxpayers eight times what they cost.

I just want to tell you how happy I am to see that this year's budget does not contain the one-third cut. That would have forced layoffs of more than 1,000 auditors last year. But that is tempered by the fact that the fiscal 1991 request is still below the enacted level for fiscal 1989 and only a modest increase over fiscal 1990.

Well, how do you expect to get the increased Medicare savings from payment safeguard activities with fiscal 1990 and 1991 spending levels below that of fiscal 1989?

Dr. WILENSKY. I am well aware of your concern about the cut that occurred with regard to the 1990 level. We have, we believe, come close to restoring the amounts that were in the fiscal year 1989 budget. And we believe the amount that is requested, $114 million, will be adequate.

Senator HARKIN. Dr. Wilensky, I refer to a table on page 67 of "Justification of Appropriations Estimates for Committee on Appropriations," the green book. Look down at the bottom line there, the total line for fiscal year 1990 shows $332.1 million in costs for a savings of $3,795.4 million. Fiscal year 1991 estimated costs of $334.8 million resulting in savings of $3,748.8 million, a net $47 million decrease in savings. Could you possibly explain that?

Ms. WILENSKY. Yes; the savings are occurring with a 1-year lag, reflecting the activities that occurred in the previous year. What you are seeing is the impact of a decline early on in 1990. Since we later went back up to our previous levels, we expect that the savings will go up. But what happens is that your savings occur following a lag from the actual activities.

Senator HARKIN. But if I look at fiscal 1989, there was a big drop from there to 1990? And then there is a big drop from 1990 to 1991? And it is less money in 1991 than it was in 1989?

Mr. MOSEDALE. I think one of the concerns that we need to outline is that there are changes from year to year in the payment safeguards effort as well. To put it bluntly, sometimes people start wising up, so we have to start changing our package a little bit.

While in fact the numbers are approximately the same in total, we have changed the makeup of payment safeguards substantially. In fact, we found we were getting a lower return on the part B side of the program, and a much higher return on the part A. So, we have shifted our effort slightly in that direction.

We also have quite a package of productivity improvements that we intend to implement this year, amounting to approximately $73 million, which will assist us in this area. So, in other words, to look at simply the payment safeguards number in total, we do not think quite presents the complete picture.

Senator HARKIN. How much could we add to this program, and still get the eight to one savings ratio? And these are hard savings, these are hard dollars. Right?

Mr. MOSEDALE. Yes, sir.

Senator HARKIN. That is what the inspector general testified to.

Mr. MOSEDALE. They are in fact audited to make sure that they are correct.

Senator HARKIN. Pardon?

Mr. MOSEDALE. They are in fact audited to make sure that they are correct.

Senator HARKIN. But I mean, if we add an additional, say, $100 million, could we expect an $800 million savings?

Mr. MOSEDALE. Yes, sir; we have not reached the limit of our return ratio.

Senator HARKIN. Pardon?

Mr. MOSEDALE. At a $100 million investment, we have not reached our maximum return.

Senator HARKIN. You still have not reached it yet?

Mr. MOSEDALE. No, sir.

Dr. Wilensky. We are not presently certain of our point of diminishing returns. We cannot say with certainty that if we were to increase payment safeguards funding, we would keep the same return ratio, but we believe there would be additional savings.

Senator **Harkin**. It seems to me you should ask for more money, then. Why are you being so reticent about it? Ask for $100 million, you will get it. We will save $800 million for the taxpayers of this country.

Mr. **Mosedale**. I guess at the risk of getting myself in trouble, last year we in fact did ask for a little bit more money. And the House side did raise our request. And when it was passed to the Senate, payment safeguards funding was in fact reduced in the contractor budget.

Senator **Harkin**. That had to do with the budget resolution and the fact that the President had a big cut in that. And when it came back to the Senate, we had to stick with the budget resolution. And then when it went back to conference, it was put back in. But it all starts with how much you are requesting here.

If I want to try to put another $100 million in I do not know where we are going to get it. But if you come down with a budget that has the $100 million in it, it sure makes a lot of difference.

Mr. **Mosedale**. I guess that my response would be that we go through the same process. And when we are trying to come to a bottom line, we are also going through the same kind of agony.

Senator **Harkin**. Well, I tell you, I had a conversation with Mr. Darman last year about this, I had a long conversation with him about it. He said he was going to take a look at it. He looked at it. Then I had a subsequent conversation with him and, basically, you are right. The inspector general is right. We are all right. This is correct stuff. But I cannot seem to get the Budget Office to move to request that additional money, or to encourage you to request that additional amount of money.

And I do not—for the life of me—I do not understand why OMB insists on not giving us the amount of money that we need to recoup those dollars. I understand at some point, it starts trickling down. But everyone I have asked from HCFA to the inspector general to everybody else says that we have not reached that yet. Even if the savings ratio was 7 to 1, or 6 to 1, we would probably still be in good shape. If we want to recoup those dollars, we have to add more money, we cannot add more money if it was not on the original budget. So, we sit there and we do not do anything. And the taxpayer is the ultimate loser. It seems like a bad way to budget things.

And I am not holding you entirely responsible, because like I said, I had this conversation with OMB, and I just cannot seem to get them to move on this issue. So, I do not know what we are going to do. I would hope you could get them to move, and come up here and request a different cut on that.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Thank you very much for being here. I appreciate it very much. I have some additional questions we will submit to you in writing.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

HEALTH CARE FINANCING ADMINISTRATION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

SOARING HEALTH CARE COSTS

Health costs have increased three times faster than the rate of inflation in this country between 1965 and 1988. Even though we spend more than other countries, the efficiency of our system is open to serious debate and our health as a nation does not appear all that superior to the other industrialized countries that often spend a great deal less than we do.

Question. What is your best advice as to how we can begin to bring these soaring health care costs under control?

Answer. Basically, we have to become more prudent purchasers of health care and assure that we are getting full value for limited health care dollars. To do this we need to reform the way we pay for health services and establish that the services we do pay for are effective and appropriate. At the same time, we must assure that all our citizens in need of health care have access to basic services.

We have already begun this process by reforming the way Medicare pays hospitals. The Medicare prospective payment system (PPS) has successfully provided a positive incentive for hospitals to operate efficiently and contain their costs. We are continuing our efforts to refine and improve PPS to insure equitable payment for the services Medicare beneficiaries require.

We are also preparing to implement reforms in the way we pay physicians. Beginning in 1992, we will use a fee schedule derived from a resource-based relative value scale that will better compensate physicians for the various types of services they provide. We will also adjust fees based on physicians meeting a volume performance standard to guard against overutilization. Until this reform is implemented, we are proposing to reduce payments for certain procedures which are clearly overpriced.

In addition, we are actively encouraging managed care options under Medicare and Medicaid to provide better integration and coordination of services within our complex health system. Organizations delivering managed care often provide more benefits, including preventive benefits, that enhance patient well-being and ultimately reduce costs.

One of the best ways to become a prudent purchaser is to pay only for care that can be demonstrated to be necessary and appropriate. The Department's effectiveness initiative will provide us with hard data to show "what works" in the practice of medicine. This important initiative may well offer the most potential for advancing the nation's health care system.

Finally, we are exploring new ways to increase access to health care for the underserved citizens of our nation. A healthier population improves the nation's economic outlook and makes health care dollars available for other priorities.

MEDICARE CUTS FROM HOSPITALS

Once again, you are targeting hospitals to achieve the bulk of Medicare savings -- about $4.1 billion -- in fiscal 1991. Yet data indicate hospital expenditures have remained virtually constant as a percent of GNP since 1982, and many hospitals appear to be barely surviving due in part to past cuts in Part A Medicare reimbursements.

Question. Why do you continue to target hospitals to achieve deficit reduction, when Medicare outlays for physicians services are rising much faster than hospital benefits?

Answer. To some degree, the $4.1 billion hospital savings figure overstates the impact of new Administration proposals. The Congress has repeatedly passed percentage reductions in Medicare's inpatient hospital capital payments. An additional year of the present 15 percent capital reduction (saving about $1 billion in FY 1991) represents continuation rather than change in HCFA's policy of providing incentives for efficient hospital capital investment.

In this budget, we have proposed outlay reductions in roughly the same proportion as each trust fund's share of total Medicare outlays. Approximately 60 percent of the cuts (or $3.3 billion) that we are proposing for FY 1991 are in Part A and 40 percent (or $2.2 billion) are in Part B. While Part B outlays are rising faster, Part A total outlays continue to grow at over 8 percent under current law in FY 1991, when the effects of the repealed Catastrophic program are removed. Difficult budget reductions must still be made in Part A, both to control this large and fast growing outlay segment and to address excessive subsidies which continue in certain types of hospital payments.

RURAL HEALTH CARE TRANSITION GRANT PROGRAM

Question. What is your rationale for not requesting funds to continue the Rural Health Transition Grant program, for which we appropriated $17,703,000 in fiscal 1990?

Answer. In FY 1990 the amount available for Rural Health Care Transition Grants is $17,761,000. HCFA is conducting an evaluation of the effectiveness and impact of the grant program on rural hospitals and their ability to provide care to Medicare beneficiaries. The results of this evaluation will formulate the basis of recommendations to Congress about the grant program.

MEDICARE COMPETITIVE BIDDING

Last year I introduced legislation calling for competitive bidding of lab services and durable medical equipment under Medicare, designed to save in excess of $1 billion annually, once fully implemented. Although this specific legislation was not enacted, Congress did further constrain lab fees, and significantly reduced Medicare reimbursement for overpriced equipment such as seat-lift chairs and TENS units. Furthermore, the law prohibiting you from conducting demonstration projects of competitive bidding for laboratory services was dropped.

Question. Do you now plan to go ahead with demonstration projects to test how competitive processes can be used to save Medicare expenditures for lab services?

Answer. HCFA is giving serious consideration to conducting competitive bidding demonstrations. In September 1985, HCFA contracted with Abt Associates Inc. to prepare a demonstration to test the feasibility of using competitive bidding as a method for acquiring laboratory services. Before this project proceeded beyond the design stage the moratorium on competitive procurement was imposed by Congress. Before the project can be implemented, the design must be updated and a new contractor selected.

QUALITY AND ACCESS ADVISORY COMMITTEE

Question. Couldn't you administratively set up an advisory committee, like the one called for in my legislation, to insure adequate protection is given to quality of services and access to care, particularly in rural areas?

Answer. Yes, HCFA believes the issues of quality and access can be adequately addressed within the context of existing rules and regulations and through proper definition of the parameters of competitive procurement.

(Background: "Competitive bidding" would actually be a way to gather price information from labs, and would be utilized to revise Medicare's fee schedules to levels reflecting the marketplace.)

OVERPRICED LAB TESTS

A recent audit by the Inspector General's Office found that Medicare was paying nearly twice as much as physicians for the same tests. You are proposing to reduce lab fee schedules in fiscal 1991, to save Medicare an estimated $60 million.

Question. Since Medicare payments for lab tests are about $4 billion annually, isn't your proposal a drop in the bucket -- less than a 2 percent cut?

Answer. Every major omnibus bill since 1984 has modified Medicare payment for clinical laboratory services. OBRA of 1989 reduced the limit on carrier fee schedules for lab tests from the national median to 93 percent of the median. HCFA agrees with the Inspector General that, in spite of past changes, Medicare still pays too much for laboratory services. The Administration proposes reducing the national cap to 90 percent for non-profile tests and 80 percent for profile and standardized test packages, making only those payment updates that do not exceed the cap, and, beginning January 1, 1993, reducing fee schedules based on discounts to physicians.

We cannot, however, make arbitrary and large reductions in laboratory service payments without examining the full effect these reductions could have on beneficiaries' access to care. Various other proposals are under consideration. To eventually establish a better estimate of the magnitude of reductions possible, we are proposing that labs supply HCFA with data on payment discounts offered to non-Medicare doctors. Total savings for our proposal will be higher because our savings estimates for this proposal do not include estimated savings from discounts.

Laboratory representatives told the Inspector General's auditors they charged Medicare more because of unnecessary billing complications.

OVERPRICED LAB TESTS

Question. Since beneficiaries don't have to pay 20 percent coinsurance for lab tests, shouldn't reimbursement be less complicated, requiring submission of bills only to Medicare?

Answer. There is evidence that Medicare pays substantially more than other payors for clinical diagnostic lab tests. The OIG found cases where Medicare paid three times the rate that physicians were charged for non-Medicare patients. We do not believe that any added complication associated with Medicare billing can explain more than a minor part of this variation. Similarly, Medicare's lack of coinsurance does not explain significant cost variation, as coinsurance charges for non-Medicare services are generally just integrated into a single bill, producing little added administrative burden.

Question. Does the fact that Medicare recipients pay nothing for lab tests result in too many unnecessary tests?

Answer. Unlike physician services and all other diagnostic tests, clinical diagnostic lab services are not subject to any beneficiary cost sharing. We suspect that this contributes to some overutilization of services; however, we cannot quantify the extent to which this occurs.

PAYMENT SAFEGUARDS

Last year's hearings convincingly showed that Payment Safeguard activities -- including pre-payment claims reviews and post-payment audits -- saved the taxpayers eight times what they cost. I am glad to see that this year's budget does not contain the one-third cut that would have forced layoffs of more than one thousand auditors last year. Yet I am disappointed that the fiscal 1991 request is still below the enacted level for fiscal 1989, and only a modest increase over fiscal 1990.

Question. How do you expect to get increased Medicare savings from Payment Safeguard activities, with fiscal 1990 and 1991 spending levels below that of fiscal 1989?

Answer. The funding requested strikes a balance between the need to safeguard program payments and the capacity of our contractors to efficiently absorb new work (such as physician payment reform and the IRS/SSA secondary payer data match). In addition, focusing of provider audit activity and improvements in medical review activities will maintain our return ratio. Given the total needs of the Medicare program and the capacity of the contractors, we believe the payment safeguard funding for FY 1990 and 1991 is prudent and responsible.

PAYMENT SAFEGUARDS

Question. How much could we add to Payment Safeguard activities and still achieve Medicare savings in a ratio of at least $8 for each $1 spent?

Answer. The FY 1991 budget estimate is based on a return ration of about 11:1. Although we do not believe we have reached the point of diminishing returns at current spending levels, there obviously is such a point. Large increases in spending would require substantial staff increases for our contractors. This would require the use of experienced staff for training and administrative activities and in the short run negatively impact savings. Incremental increases would be the wiser choice. Although we don't think it is necessary, we believe it is likely that an additional $100 million could be added over the next two to three years without diminishing the current return ratio.

IMPLEMENTATION OF SECONDARY PAYER REFORMS

The Omnibus Budget Reconciliation Act of 1989 (OBRA-89) contains new provisions to greatly strengthen enforcement of the Medicare secondary payer laws. These are the situations where an employer's health benefit plan is responsible for paying claims rather than Medicare. These provisions were supposed to save over $300 million this year and even more next year.

Question. What is the status of the implementation of these savings reforms and when do you expect to see results?

Answer. The majority of the effort and expenditures in FY 1990 will be to implement the program changes relating to the Medicare secondary payer program. In FY 1991 we should begin to see the savings from these initiatives. For example, we now expect the IRS/SSA data match to produce about $400 million in savings in 1991.

Question. Why have you cut this area in your fiscal 1990 operating plan at a time when Congress and the administration have both been emphasizing the need for greater efforts in this area?

Answer. The total MSP budget is reduced in FY 1990 from FY 1989. However, the reduction is in Part B of MSP, whereas Part A MSP activities have been increased in FY 1990. Part A MSP expenditures have a return ratio much greater than Part B; accordingly, we are concentrating our dollars toward the area of greatest return.

Question. Have you requested additional funds in your fiscal 1991 budget to ensure that these new savings initiatives can succeed?

Answer. The FY 1991 budget contains a request for $8 million within the outlayed contingency for funding the IRS/SSA data match.

Question. What other proposals do you have in this area to prevent the payment of health claims where Medicare is not responsible for them?

Answer. We have no current plans for requesting new legislation. Implementing the new IRS/SSA data match and continuing our efforts with other aspects of the MSP program will continue to return significant program savings. OBRA 89 precludes us from requiring Medicare contractors and other third party insurers to match payment information from private enrollees against Medicare records.

CRACKING DOWN ON UNBUNDLING

According to press accounts, Blue Cross and Blue Shield of Illinois is cracking down on "unbundling", a billing practice some doctors use to double or triple their fees. A hysterectomy, for example, might be broken down into several components and fees charged for each part to raise billings far beyond the standard operation. Illinois Blue Cross reportedly expects to save $25 million annually by programing its computers to catch such abuses, and automatically adjusting the payment amount to the proper fee.

Question. Isn't this the kind of abuse we ought to be stopping nationwide?

Answer. Yes, each Medicare carrier applies local policies in addressing unbundling. HCFA is currently planning to conduct a review to capture the best features from each carrier and develop guidelines to be followed at all carriers.

Question. Why don't you require all of your 86 Medicare contractors to install Payment Safeguard computer programs like the one developed by Illinois Blue Cross?

Answer. Medicare carriers apply local policies that address unbundling. These policies, to varying degrees, accomplish essentially the same objective as the Illinois Blue Cross and Blue Shield computer applications; *i.e.*, rebundling of services with appropriate adjustment of payment levels. We plan to study the Illinois process as well as conduct a review of the carrier policies to determine the best features that HCFA would then require of all carriers.

Question. Are you aware of other innovative Payment Safeguard techniques utilized by individual Medicare contractors that could be applied throughout the United States?

Answer. HCFA is planning to take advantage of new tools and technologies that are available in the claims process to sharpen an already innovative program. These include use of the ICD-9-CM diagnosis coding based screens, profiling on the Unique Physician Identification Number (UPIN) of both the ordering and referring physician and utilizing the Common Working File to perform a more comprehensive review of services received by a Medicare beneficiary in all treatment settings.

PHYSICIAN PAYMENT REFORM

Congress enacted an entirely new payment program for physician services as part of the 1989 reconciliation legislation. This includes an entirely new fee schedule for physician payments, a limit on overall payments, and limits on billing patients above Medicare's approved amount.

Question. Are you fully committed to implementing these reforms, without seeking legislative change?

Answer. Yes.

PHYSICIAN PAYMENT REFORM

Question. Tell us about the savings you expect from these reforms. How do you expect these payment changes to modify the incentives under the current system that tend to favor surgery and other high cost specialty services over primary care?

Answer. The Omnibus Budget Reconciliation Act of 1989 (OBRA 89) creates a national Medicare fee schedule for physicians' services based on a Resource-based Relative Value System. We believe that this fee schedule will resolve many of the inequities of the current system. Under physician payment reform, physicians will be paid an amount determined by taking the product of three elements: (1) a relative value for the services (based on physician work, professional liability insurance and other overhead expenses); (2) an appropriate geographic cost of practice index (GPCI) for the locality so that the payment amount will incorporate the relative costs of providing services in the locality and (3) a conversion factor to determine a dollar payment amount. The relative values, GPCIs and conversion factors will not vary by specialty of a physician.

The law implementing physician payment reform requires that payments to physicians under the RBRVS fee schedule be budget neutral. We expect that savings from payment reform will only come from the Medicare volume performance standard (MVPS). This standard is not a limit on overall payments, but rather a target for growth in volume and intensity of services that may, in the second subsequent year, affect the rate of increase in physician payments.

The law anticipates that the MVPS will be set each year by Congress, but the law provides a default mechanism for the Secretary to use in setting the MVPS if Congress does not act. The Secretary must monitor and report regularly on the extent to which the MVPS is being met or exceeded. Congress may take MVPS compliance into consideration when establishing the annual update for physician payments or may permit a default mechanism to establish the update.

Preliminary analyses indicate that the RBRVS based payment system should result in a greater proportion of physician payments being directed towards evaluation and management services (i.e. visits) generally provided by primary care physicians. Therefore, payments for surgical services and other specialized services are likely to be reduced. Of course the effect on particular physicians will vary depending upon their location of practice and mix of services provided.

Question. What's to keep surgeons from raising fees on other patients to make up for lost income from Medicare?

Answer. While some surgeons may charge non-Medicare patients more to make up reduced Medicare revenues, there are market factors that we expect to restrain the extent to which this happens. For example, other third-party payors--particularly employer sponsored plans and Medicaid--will certainly resist raising their payments to make up for any reduction in Medicare. In addition, some third-party payors may eventually adopt RBRVS systems similar to Medicare's.

MAKING THE HEALTH CARE SYSTEM MORE EFFICIENT

It has been said that our health care system just doesn't have the right incentives to make employers, the government, and consumers demand cost efficiencies. Most bills are paid through insurance companies, giving neither providers of services nor recipients much concern over costs, as long as someone else is picking up the bill.

One proposal being advanced would require employers to offer all full-time employees a choice of qualified health plans. For each plan offered, the employer would obtain a quotation for the price of basic coverage. The employer's contribution would then be 80 percent of the weighted average of those prices.

Question. What is your reaction to this proposal?

Answer. I believe you are referring to the Enthoven-Kronick "Consumer Choice" model for health insurance for all Americans. As vice-chair of the Department's task force addressing issues concerning the uninsured and long term care, I can tell you that we are discussing many proposals including those similar to the one you cite. I also look forward to reviewing the recommendations of the Pepper Commission and the Advisory Council on Social Security. It would be premature to make any comment on specific proposals before the task force completes its work and makes its recommendations this Fall.

(Background: Organized labor allegedly opposes this proposal, which is reportedly gaining ground with members such as Sen. Durenberger and Congressman Gradison.)

MEDICARE REIMBURSEMENT FOR WHEEL CHAIRS

I have heard from disability groups that there is a problem with purchasing wheel chairs under Medicare. The Omnibus Budget Reconciliation Act of 1987 placed wheel chairs under a category which only allowed for fifteen months' rental and no purchase. Vendors are then required to continue to provide the chairs to an individual for life with no reimbursement beyond the rent from the first fifteen month period. Thus vendors are reluctant to enter into agreements with people who have long term needs even though Medicare had, in fact, paid the equivalent of 150 percent of the submitted purchase price by the end of the fifteen months.

Not being able to purchase a wheel chair, and having difficulty in renting a chair through Medicare is devastating for a person with a disability who is dependent on a wheel chair every day of their life. Mobility is fundamental to a person's quality of life. It means being able to get to work, go out to eat, go to church, see a movie. This situation is untenable.

An attempt was made to correct this situation when we passed the Reconciliation Act last year.

Question. What additional do we need to do to fix this problem?

Answer. Allowing Medicare to purchase manual wheelchairs would require additional legislative change. Prior to OBRA of 1987, Medicare carriers paid for DME such as wheelchairs on the basis of rental or purchase, depending on what was more economical. The carrier's decision was based on the physician's prescription, the expected period of need, and the beneficiary's health status. If purchase was more economical, the beneficiary was notified that Medicare would pay no more in subsequent rental charges than would be paid if the equipment had been purchased. In the past, however, Medicare purchased a large number of wheelchairs for individuals who did not need them or only required them for a short period of time.

OBRA of 1987 provides a detailed methodology by which carriers pay for the six categories of DME. OBRA 87 prohibits payment for manual wheelchairs -- which are "capped-rental" items -- beyond the 15th rental month except for semi-annual maintenance and servicing payment. After Medicare pays for 15 months of rental, the supplier must continue furnishing the item to the patient without any charge, other than for maintenance and servicing, until the medical necessity ends or Medicare coverage ceases.

Organizations representing DME suppliers strongly supported OBRA 1987's changes to rental only. Should purchase of manual wheelchairs be allowed again in the future, it must be accompanied by sufficient safeguards to prevent program abuse.

Question. It seems that in the Reconciliation Act of 1989, when we created a separate category for motor driven wheel chairs that would allow purchase of those chairs by people with chronic disabilities, we did not include push wheel chairs under the same category. It makes no sense to deny people the opportunity to purchase push chair.

Is this something you feel you could change administratively? Or if not, would you support a change in statute to allow for the purchase of push chairs?

Answer. HCFA does not feel that it could allow purchase of manual wheelchairs in the absence of a legislative change. Section 1834 of the statute is explicit in delineating the items in each category of durable medical equipment (DME). Manual wheelchairs, since they are not purchased more than 75 percent of the time, fall in the category for "Other Items of DME". Items in this category may only be rented. A monthly rental payment is made to the supplier for 15 months after which the supplier is obligated to continue providing the item to the beneficiary for the duration of medical need.

HCFA agrees that, in certain instances, it would make sense to allow beneficiaries the opportunity to purchase push wheelchairs. HCFA plans to explore various alternatives to modifying the payment system to allow for purchase of this type of equipment, while putting in place safeguards to prevent unnecessary purchases of this relatively expensive equipment in cases where short-term rental is preferable.

Repairs are cited as a problem. While the chair is being rented, repairs must be done by the vendor. This is pretty hard on someone who rents in Los Angeles and is in Chicago on business, for example, and the chair breaks down. They must pay for the repair themselves.

Question. Can we change that?

Answer. Medicare includes payments for the cost of repairs on rented wheelchairs in the rental payment amount. If a beneficiary's purchased wheelchair needs repair, Medicare would pay the reasonable charge of repairing the item. It makes no difference if the wheelchair needs the repair while the beneficiary is out-of-town or at his usual residence. (Manual wheel chairs, however, may only be rented, not purchased, since OBRA of 1987 took effect.) We would expect that if the beneficiary's rented item of equipment needed repair while out-of-town, the beneficiary would obtain servicing from an out-of-town supplier and submit the bill for reimbursement to the supplier providing the equipment. We expect suppliers renting equipment to honor a bill for emergency repair from an out-of-town supplier. We believe that this process has been working well since the inception of the Medicare program.

I also hear from people that Medicare is still denying claims for purchase of motor driven wheel chairs, even though the changes to allow purchase were to go into effect January 1.

Question. How can we implement this change more quickly?

Answer. Prior to OBRA 89, power driven wheelchairs were treated as miscellaneous durable medical equipment. Under this classification, payments were made on a rental basis. Effective January 1, 1990, power driven wheelchairs are defined as routine durable medical equipment and may be rented or purchased. HCFA sent instructions to its carriers in November 1989 to implement the change. We are currently reviewing each carrier's procedures to assure compliance with the new instructions.

(Background: The national office notified the regional offices on November 30, 1989, to make the change; regional offices are then to tell Medicare contractors to implement the change. In Iowa, it appears that the Blue Cross-Blue Shield contractor made the change effective February 5, 1990.)

DEFENSIVE MEDICINE

The American Medical Association estimated that it cost the health care system $12 to $14 billion in 1988 for defensive medicine--extensive tests and procedures performed by doctors to protect themselves from being sued for malpractice. Some of these tests are clearly unnecessary and do not benefit patients.

Question. What can you propose to stop this wasteful spending?

Answer. We continue to examine ways to insure the integrity of Medicare and Medicaid payments. The best approach, of course, is to provide incentives for appropriate utilization of services. With this in mind, we are proposing new options for managed care to provide integrated and coordinated services to Medicare and Medicaid patients.

We are also actively participating in the Department's effectiveness initiative to study the outcomes of patient care and determine "what works" in the practice of medicine. Physicians will be able to rely on proven treatments and procedures which should lessen the incidence of malpractice.

We also have several mechanisms in place to assure that we pay only for medically necessary services. Our Medicare carriers, who pay part B bills for laboratory and physician services, review claims to assure the necessity of services provided. Peer review organizations review physician practice patterns to determine if services are being provided within certain quality and utilization norms. Review will be more intensely focused on practice patterns which appear to be aberrant.

Hospitals have been closely monitoring the provision of services, especially ancillary services, in order to operate efficiently and effectively under the Medicare prospective payment system.

PAPERWORK

The Health Care Financing Administration is often criticized for requiring too much paperwork, imposing unnecessary burdens on health care professionals, and inhibiting direct services to Medicare and Medicaid recipients.

Question. What are you doing to streamline the processing of Medicare and Medicaid claims?

Answer. The Medicare Program has become more and more complex in recent years as Congress has enacted changes in coverage and payment policy to achieve savings in the annual budget reconciliation process. These changes often increase the complexity of the claims process for providers and for HCFA's contractors.

As a practical matter, the best way for physicians and contractors to deal with this ever-increasing complexity is to move away from reliance upon the filing of paper claims to the electronic submission of claims. HCFA has been examining its electronic claims filing policies and procedures. As required by the Omnibus Budget Reconciliation Act of 1989, HCFA will be submitting a report to the Congress with its recommendations for encouraging providers to submit their claims electronically. We are always diligently determining the impact of current paperwork requirement on Medicaid claims processing and seeking innovative solutions to unnecessarily burdensome aspects of those requirements.

Question. Do you conduct cost/benefit analysis of your paperwork requirements, to determine if the data is worth the cost?

Answer. Cost benefit analysis of the majority of data collected in administering the Medicare and Medicaid programs is not done. This is due to the fact that data collected are essential to assure adequate and proper payment of claims. However, HCFA is continually evaluating and revising its information collection activities to minimize data requested from beneficiaries, fiscal intermediaries and contractors, and providers of health care services. HCFA consults with representatives of these various groups during the development of many of our data collection instruments. This involvement ensures that the paperwork burden of these instruments is properly assessed and is as minimal as statutory requirements allow.

Through the joint efforts of users and HCFA, our two most burdensome forms (HCFA-1500 and HCFA-1490, Health Insurance Common Claims Form for Medicare and Medicaid) have been revised to eliminate any HCFA data requirement that is not essential to processing the claims for proper payment--a savings of over 28 million hours of burden annually. Further burden savings are achieved as the levels of electronic media claims processing of the two forms increase, decreasing the number of paper claims.

Question. What system do you have to insure that regulatory proposals are in compliance with the Paperwork Reduction Act?

Answer. HCFA's regulations development and clearance process requires that each proposed regulation be reviewed by an internal paperwork management staff to determine applicability of the Paperwork Reduction Act. Regulations that contain information collection requirements are tracked by this staff through the various stages of development, including publication in the *Federal Register*, until "final." All *Federal Register* comments received from the public during this development process are also reviewed for paperwork burden implications. Once the regulation is "final," HCFA then submits a request to the Office of Management and Budget for approval of the information collection requirements as prescribed in the Paperwork Reduction Act (PRA).

This review and monitoring is done not only for compliance with the PRA, but also to ensure that HCFA's regulations impose the least prescriptive requirements possible, resulting in less burden. These efforts are sometimes limited, however, because of specific statutory requirements which we must implement

RISK-BENEFIT RATIONING

Dr. James Todd, a senior official of the American Medical Association, recently suggested that "risk-benefit rationing" would be a way to control soaring health expenses. In risk-benefit analysis, the risk of a particular surgical, or medical, procedure is measured against the potential health benefit.

Question. Wouldn't "risk-benefit" analysis unfairly target the elderly?

Answer. Without a full explanation of what Dr. Todd means by "risk-benefit rationing," it is difficult to fully respond to the question. Nevertheless, we see no need for "rationing" that would deprive the elderly of essential or necessary care.

There is no question that there has been a proliferation of medical procedures and treatments whose ultimate value to the patient is questionable. For this reason, the Department encouraged, and the Congress enacted, the establishment of a program of research on outcomes of health care services and procedures within the Agency for Health Care Policy and Research (AHCPR). By undertaking and supporting this research through the AHCPR's Medical Effectiveness Treatment Program (MEDTEP), we will be better able to inform both physicians and patients of the risks and benefits to the patient of alternative procedures and treatments. The primary focus of the MEDTEP program is, and will continue to be, improved quality of care for the Medicare beneficiary.

Question. How much of one's health care costs are incurred in the last two weeks of life?

Answer. There is no data on that question because it would involve following an individual's health care costs from birth to death. Based on a study in the Spring 1984 *Health Care Financing Review*, we know that 28 percent of Medicare expenditures for aged enrollees went for enrollees in their last year of life, 21 percent for enrollees in their last 6 months of life and 8 percent of enrollees in their last month of life. The data reflect Medicare expenses for covered services and, thus, exclude most nursing home and prescription drug costs. The data are from 1978 and work is underway to obtain more recent data.

Question. How expensive would it be to gather the necessary data on risks and outcomes?

Answer. Without a full explanation of what Dr. Todd means by "risk-benefit rationing," it is difficult to comment on the cost of obtaining the necessary data.

- Each of the four Patient Outcome Research Teams (PORTs) funded by the Agency for Health Care Policy and Research (AHCPR) through its Medical Treatment Effectiveness Program (MEDTEP) is gathering data on risks of alternative treatments and the resulting patient outcomes for a particular illness significant for Medicare beneficiaries.
    - Each PORT will run 5 years and be funded at approximately $1 million per year.
    - The costs of undertaking a "risk-benefit" analysis of a specific researchable area of illness would be at leas $5 million over 5 years.

MEDICAID DRUG PRICES

Medicaid drug costs now exceed $3 billion annually. Prices for the same drug can vary widely among suppliers, and some hospitals and health maintenance organizations have been able to negotiate steep discounts for volume purchases.

Question. How many State Medicaid programs currently take advantage of group discount purchasing to save money on prescription drugs?

Answer. It is my understanding that 18 States have restricted drug formularies or lists of Medicaid approved drugs which may take advantage of group discount purchasing. It should also be noted that Kansas has the only Medicaid drug program which uses a competitive bidding process to obtain discount prescription drug prices.

Question. What can be done administratively to encourage States to save Medicaid funds through discount buying?

Answer. At the present time, unfortunately, very little. HCFA in the past has encouraged States to engage in volume purchasing for prescribed drugs because of the potential for significant savings. However, we have been unable to assist the States in overcoming their major problem of the refusal of drug manufacturers to submit bids. This is because HCFA has no direct relationship with drug manufacturers, since we match State expenditures for drugs and the States provide payment for the drugs through pharmacy providers.

Question. Would you favor legislation to mandate that States establish programs to negotiate lower drug prices?

Answer. We would support States' efforts to negotiate lower prescription drug prices. In fact, we require State Medicaid programs to purchase drugs at an "estimated acquisition cost", a price below the "average wholesale price."

States have attempted to negotiate lower drug prices with drug manufacturers but, to date, have been largely unsuccessful. Legislation could help provide States leverage to obtain drugs for their Medicaid programs at a lower or discounted price.

PEER REVIEW ORGANIZATIONS

You contract with Peer Review Organizations (PROs) to check hospital records, and report on improper or unnecessary care. Studies have recommended expansions of PRO activities improve the effectiveness of the program in containing Medical costs and assuring quality of care. According to your own data,, the PRO program is already saving at least $1.10 for every $1.00 spent in Medicare funds. This estimate does not include savings from preadmission review activities or any savings from the "sentinel effect" of the program in deterring unnecessary and inappropriate utilization.

Yet we are spending less than a fraction of one percent Medicare outlays on the PRO program. Evaluations of the program by the General Accounting Office and others have found that the PROs could save considerably more if their utilization review activities were expanded and targeted more to preadmission review of hospital stays.

Question. Are we underfunding the PROs?

Answer. No. The OMB apportionment for all third round PRO activities is $955 million. This includes $10.6 million for pilot studies and $110.8 million to implement the regulations for review of substandard care and the second surgical opinion program. The amount remaining for funding third round PRO activities contained in the current scope of work is $833.6 million ($955.0 million less $10.6 million less $110.8 million).

We have negotiated third round contracts with 51 of the 53 PROs (Virgin Islands and Hawaii/American Samoa/Guam were extended to June 30, 1990) at a cost of $801.2 million ($775.2 million for activities required in the scope of work plus $26 million for photocopy pass-through costs). This amounts to 96.1 percent ($801.2 million divided by $833.6 million) of the total amount available to fund third round PRO activities contained in the current scope of work.

Question. Could we achieve much greater savings by substantially increasing PRO funding?

Answer. No. Since the beginning of the PRO program, we have refined the scope of work to focus in on those areas where we can obtain the greatest return on our investment of resources. During the first scope of work, we reviewed approximately 48 percent of all inpatient admissions. During the second scope of work, the review level dropped to approximately 25 percent of inpatient admissions. During the third scope of work, we anticipate that PROs will review approximately 17 percent of inpatient admissions.

Also during the third scope of work, we increased our mandatory review of preadmission procedures from 5 to 10 procedures. We do not believe that substantially increasing PRO funding, and consequently increasing PRO review, would be cost effective. The areas in which we focus our review have proven to be the most productive. To increase review in non-productive areas would not be cost effective and would not increase savings.

Question. Are the PROs currently being funded at a level that encourages adequate attention to their quality assurance role?

Answer. Both HCFA and the PROs recognize that quality review is one of the PROs' primary review functions.

- o To further enhance the PROs' role in this area, HCFA has increased PRO quality review responsibilities in the third Scope of Work, and the PRO budgets provide adequate funding to support these activities.
- o PROs are now paid, in part, on a "per review" basis versus the prior fixed price contract. As a result, funding levels are commensurate with the review levels.

INCENTIVES FOR HEALTH MAINTENANCE ORGANIZATIONS

Your budget proposes to increase Medicare payments to health maintenance organizations by 5 percent. I understand your objective is to increase the attractiveness and availability of "managed care" options aimed at controlling the growth of health costs. Yet GAO, in a November 1989 report, indicated that Medicare may already be paying more for HMO enrollees than if they had remained in the fee-for-service sector, despite the intent of Congress that Medicare should save 5 percent from HMO's compared to the fee-for-service sector.

Question. Why should we further increase HMO rates if GAO has evidence that payments are already too high?

Answer. We support increasing the adjusted average per capita cost (AAPCC) payment levels for Medicare risk-contracting organizations for a number of reasons:

Having AAPCC payments equal expected fee-for-service payment levels will result in a "level playing field" in HCFA's treatment of different types of providers. Providers who participate in managed care systems should not be penalized for their willingness to participate in an organized health care delivery system that provides services to Medicare beneficiaries.

Except in a few areas of the United States, 95 percent of the AAPCC is considered an insufficient payment level for many commercially successful (and cost-effective) HMOs to enter into Medicare risk contracts. Increasing the payments to 100 percent will increase the number of organizations willing to serve the Medicare population.

Among the organizations that have failed to renew Medicare risk contracts since the risk program began, the overwhelming majority have cited inadequate funding as the primary reason for non-renewal.

Increasing payments to 100 percent of the AAPCC will result in HMOs contracting anew in rural areas which have witnessed the termination of previous Medicare risk contracts. In addition, beneficiaries in other areas of the country where there were no risk contracts will have the HMO option available to them.

Increasing the availability of the Medicare HMO option will result in potentially higher quality care, improved access to care, and rational use of health providers through an organized delivery system.

Question. Are there not other ways to encourage "managed care" without spending the extra $180 million in 1991?

Answer. Increasing payments to Medicare risk contractors is not the sole avenue HCFA is pursuing in seeking to expand managed care. HCFA is encouraging managed care through current options available under the law, and by proposing new legislation that will expand managed care options for Medicare beneficiaries and Medicaid recipients. Some of the new proposals will not result in additional cost, and may produce savings. In Medicare, for example, there is the "Medicare Plus" proposal, which permits coverage of Medicare beneficiaries through managed care organizations combined with insurers that will offer Medigap coverage. In Medicaid, there are proposals that are intended to encourage States to promote Medicaid managed care, as well as a proposal to simplify the administration of Medicaid managed care for organizations participating in Medicaid.

At the same time that new managed care proposals are being considered, HCFA continues to support expansion of the Medicare risk contracting program. HMOs and CMPs are the purest form of managed care and have distinct advantages over fee-for-service care, including, for example, improved access to care, appropriate care rendered by the appropriate provider, and quality assurance systems that are not found in fee-for-service Medicare. Enrollment in Medicare risk contracts has remained relatively static over the past couple of years at the level of one million beneficiaries enrolled in risk health maintenance organizations (HMOs) or competitive medical plans (CMPs). Increasing payments to risk HMOs and CMPs will induce more organizations to participate as Medicare risk contractors. Since the payment increase proposal also includes a provision for a beneficiary Part B premium rebate, there should be higher enrollment in current HMOs/CMPs as well as enrollment in newly-contracting HMOs/CMPs.

RURAL HEALTH CARE TRANSITION GRANTS

Question. How many awards to rural hospitals do you expect to make with fiscal 1990 appropriations of $17,761,000 for the Rural Health Care Transition Grant program?

Answer. About $8.5 million of this appropriation is required for the second year continuation of grants awarded in FY 1989 and for the evaluation required by statute. Therefore, about $9.2 million will be available for new grants. Assuming all hospitals request the maximum funding allowed of $50,000 per year, we expect to award about 185 new grants in fiscal 1990.

Question. How much will be needed in fiscal 1991 to sustain these grants for a second year?

Answer. About $9.2 million would be needed for the second year of these grants awarded in fiscal 1990.

Question. What is your timetable for issuing second-year grants with fiscal 1990 appropriations, as well as new grants for fiscal 1991?

Answer. We expect to send out continuation applications for the second year grants from fiscal 1990 appropriations in May. These applications must be received by HCFA by July 15, 1990 with the grants awarded September 15.

For new grants to be awarded in fiscal 1990, grant kits were mailed to each eligible rural hospital on February 1, 1990. All applications must be received by HCFA by May 1, 1990. They will be reviewed by external reviewers during June and by HCFA during July and August. Awards will be made in September.

If funds are made available in FY 1991 for the grant program, new awards would most likely follow the same monthly timeline as noted above for the new FY 1990 grants, but within FY 1991.

PHYSICIAN PAYMENT REFORM

Congress also enacted an entirely new payment program for physician services as part of the 1989 reconciliation legislation. This includes an entirely new fee schedule for physician payments limit on overall payments, and limits on billing patients above Medicare's approved amount.

Question. Tell us about the savings you expect from these reforms. Also, how do you expect these payment changes to modify the incentives under the current system that tend to favor surgery and other high cost specialty services over primary care?

Answer. The Omnibus Budget Reconciliation Act of 1989 (OBRA 89) creates a national Medicare fee schedule for physicians' services based on a Resource-based Relative Value System. We believe that this fee schedule will resolve many of the inequities of the current system. Under physician payment reform, physicians will be paid an amount determined by taking the product of three elements: (1) a relative value for the services (based on physician work, professional liability insurance and other overhead expenses); (2) an appropriate geographic cost of practice index (GPCI) for the locality so that the payment amount will incorporate the relative costs of providing services in the locality and (3) a conversion factor to determine a dollar payment amount. The relative values, GPCIs and conversion factors will not vary by specialty of a physician.

The law implementing physician payment reform requires that payments to physicians under the RBRVS fee schedule be budget neutral. We expect that savings from payment reform will only come from the Medicare volume performance standard (MVPS). This standard is not a limit on overall payments, but rather a target for growth in volume and intensity of services that may, in the second subsequent year, affect the rate of increase in physician payments.

The law anticipates that the MVPS will be set each year by Congress, but the law provides a default mechanism for the Secretary to use in setting the MVPS if Congress does not act. The Secretary must monitor and report regularly on the extent to which the MVPS is being met or exceeded. Congress may take MVPS compliance into consideration when establishing the annual update for physician payments or may permit a default mechanism to establish the update.

Preliminary analyses indicate that the RBRVS based payment system should result in a greater proportion of physician payments being directed towards evaluation and management services (i.e. visits) generally provided by primary care physicians. Therefore, payments for surgical services and other specialized services are likely to be reduced. Of course the effect on particular physicians will vary depending upon their location of practice and mix of services provided.

Question. What actions do you expect to take this year and in fiscal 1991 to implement the new physician payment system? What funds have you requested to ensure that these reforms are implemented on schedule?

Answer. With respect to Medicare contractors, HCFA is taking the following implementation steps:

FY 90

Develop uniform physician payment conventions to eliminate local payment variations (such as global surgeries) as identified in HCFA's Report to Congress in October, 1989.

Establish policies and procedures for implementing the mandatory claims submission requirement by September 1,1990.

Develop policies and procedures for implementing the requirement to profile physician utilization.

Prepare a report to Congress on recommendations to encourage the electronic submission of claims.

Develop and implement carrier requirements for a comprehensive provider education and training initiative on each aspect of physician payment reform.

FY 91

Implement uniform physician payment conventions.

Implement revised Explanation of Medicare Benefits Forms.

Develop and implement policies and procedures for calculating fee schedule transition payments and actual charge limits.

In addition to contractor activities, HCFA will be undertaking numerous internal activities in FY 1990 and 1991.

- 1990 will be devoted to development of data and methodology needed for the fee schedule, including publication of a model fee schedule;
- There will be much consultation with the PPRC and physician organizations as we perform our analyses and make the decisions needed to implement physician payment reform.
- We will be actively addressing such issues as coding definitions, coding modifiers, site of service differentials, etc.
- These activities will continue in 1991 when we will publish the fee schedule as an NPRM for comment and as a final later in the year.

FY 1990 Actions:

- 1990 Medicare volume and performance standards (MVPS) published December 29, 1989;
- 1991 MVPS recommendation due to Congress on April 15, 1990;
- Model fee schedule to be published on September 1, 1990;
- Definition of surgery published by April 15, 1990;
- Default MVPS methodology published in Spring of 1990.

FY 1991 Actions:

- NPRM containing the first year proposed fee schedule to be published in early 1991;
- 1992 MVPS recommendation due to Congress April 15, 1991;
- 1992 Medicare payment update recommendation due to Congress on April 15, 1991;
- Report to Congress on use of time in visit code definitions to be submitted on July 1, 1991;
- Final regulation containing 1992 fee schedule to be published in late 1991.
- Implementation of coding changes, including elimination of local codes;
- Preparation of instructions to carriers;
- Carriers' systems changes to accommodate the fee schedule.

Question. What assistance will be available to Medicare beneficiaries and health care providers to understand these changes when they are made?

Answer. Beneficiaries:

HCFA will revise the Medicare Handbook to include a description of all pertinent changes.

HCFA will revise its Explanation of Medicare Benefits (EOMB) forms to inform beneficiaries of how their payments are computed under the fee schedule.

HCFA will develop training materials on each aspect of payment reform for use by carriers and senior citizen organizations in educating beneficiaries.

Providers:

HCFA is planning a 2-point provider education and training strategy.

HCFA has developed a comprehensive plan for using its carriers to train physicians and their staffs on each key provision. Carriers will do such things as:

Meet regularly with State and local medical societies to explain implementation policies and procedures.

Publish HCFA-prepared articles on each provision in their regular bulletins and newsletters.

Conduct seminars and workshops on each provision for physicians and their staffs.

Increase their telephone and correspondence staffs to respond to physician inquiries.

Establish a speaker's bureau to respond to requests for presentations on key provisions.

HCFA will also develop a joint provider education plan with the American Medical Association, which has offered its public information services such as publications, seminars and training material development.

MEDICARE PREMIUMS

The dramatic rise in health care costs is directly evident to Medicare beneficiaries, who have to pay premiums equal to 25 percent of total Medicare expenditures. From 1970 to 1980, premiums rose from $5.30 per month to $9.60 per month. By 1985, the premium was $15.50 per month. Now, in 1990, the premium will be about $29 per month, despite repeal of the catastrophic surcharge.

Question. What is your projection of the increased premiums that Medicare beneficiaries will have to pay over the next few years?

Answer. The following table compares estimates of Part B premium increases under two different streams. The first shows what premiums would look like if no legislative changes occurred, with premiums increasing by the previous year's COLA. The second shows the premium stream if premiums are set at 25% of program costs for the aged and assumes no program savings.

	1991	1992	1993	1994	1995
Current Law (with COLA increase)					
	$29.90	$31.10	$32.40	$33.60	$34.80
Current Law (with premiums set at 25% of program costs for the aged)					
	$31.30	$35.20	$39.80	$44.70	$50.10

Question. Would you favor limiting the rate of growth of Medicare premiums?

Answer. The Administration proposes limiting the growth in beneficiary premiums by comprehensively reducing Part B outlays. OBRA of 1989 extended the 25% premium methodology through CY 1990. In 1991 the percentage increase in the premium will be linked to the Social Security cost-of-living adjustment (COLA). If Congress maintains the 25 percent provision without reducing outlays, the premium would be $3.00 per month more than under proposed law. Under our proposal, beneficiaries would continue to remain protected by the hold-harmless provision if the amount of an individual's premium increase is greater than their social security COLA.

The following table shows proposed premiums:

Medicare Part B Premiums

	1991	1992	1993	1994	1995
Proposed Law	$29.90	$33.30	$37.30	$41.90	$47.10

Question. How else can we better control fraud, waste and abuse that contribute to excessive Medicare costs?

Answer. We don't believe fraud and abuse have been the primary factors contributing to increased Medicare premiums. Our studies indicate that the growth in the Medicare part B premium has several causes. About 15 percent of the growth is due to the increase in the age and number of Medicare beneficiaries; about 40 percent of the growth is due to increased prices; and about 45 percent of the growth is due to increases in the volume and intensity of services. It is in this last category that excessive utilization may be causing unwarranted Medicare expenditures. However, under the recently enacted physician payment reform, volume performance standards will set levels for acceptable volume increases. Future payments will be adjusted to reflect the degree to which the standards have or have not been met. In this way, reasonable volume increases can be accommodated while curbing Medicare expenditures for unnecessary services.

Question. The Medicare program is increasingly plagued with durable medical equipment companies who operate across state and regional boundaries in an effort to obtain the maximum reimbursement for their product, obtaining provider numbers from a multitude of Medicare carriers. Since provider numbers are the "keys" to unlocking Medicare funds, what controls has HCFA instituted to prevent DME providers from submitting Medicare claims to a multitude of carriers and/or to the carrier who pays the most for a particular item or service?

Answer. HCFA is disputing a number of suppliers claims as to their billing jurisdictions. We are pursuing the recoupment of overpayments in these cases.

The current claims jurisdiction policy for durable medical equipment, orthotics, prostheses and supplies is dependent upon the "point of sale." This policy, which was convenient when most of such products were purchased at local pharmacies, is inadequate to deal with multi-State companies.

We are currently conducting a large scale study to determine the costs of the present jurisdiction policy and the costs of several alternative policies. In addition to cost, consideration is also being given to important factors such as the effect on the Common Working File, economies of scale in claims processing and the convenience of beneficiaries and suppliers. Regions and carriers have been alerted to audit equipment suppliers with large numbers of out of area claims.

Question. Medicare reimbursement for parenteral and enteral nutrition (PEN) therapy, as it presently exists entails substantial costs to the Medicare program. As seen from allowances reported in Blue Cross and Blue Shield of South Carolina's "PEN Supplier's Guide to Medicare", dated August, 1988, the monthly cost of nutrient may be as high as $2000-$5000 per patient per month; the allowance for the monthly rental of an infusion pump is $300 per month; while the allowance for a PEN administration kit is $600 per month. In order to contain these extremely high reimbursements by the Medicare program, what oversight activities has HCFA instituted at the two specialty carriers?

Answer. Certification forms signed by a physician justifying the need for PEN therapy must be submitted. Claims are selected for special postpayment review by the two PEN specialty carriers. A protocol to review PEN carrier operations is being developed. OBRA 89 contained a provision to limit rental payments for pumps to 15 months. A legislative proposal to create an enteral fee schedule has again been submitted.

Current program cost containment efforts are focused on utilization controls and reviews for medical necessity. We work continuously with the carriers to target postpayment review activities and to strengthen prepayment computer edits and medical review guidelines. While these activities are essential, and effectively reduce the costs per patient from those paid before the creation of the two specialty carriers for PEN claims, the cost per patient is still very high. The higher costs noted in the question refer to parenteral rather than enteral patients; parenteral patients represent less than 10 percent of the PEN patient workload. (Parenteral is for those patients who cannot digest; enteral for those who cannot swallow.)

OBRA 86, sec. 9340, mandated the use of charges as the payment basis for parenteral and enteral products. Since then we have submitted several legislative proposals to reprice enteral and parenteral products and place payment under a fee schedule. Our current budget asks again for this authority.

(We also need a technical amendment to the pump rental provision (OBRA 89, sec. 6112). This provision, while limiting pump payment to 15 months, does not prohibit purchase of the pump as is explicit in other rent/purchase legislation. It also failed to link the amount of the rental payments to the purchase cost).

ADEQUACY OF FISCAL 1991 REQUEST

Your request for Medicare's administrative operations clearly does not keep pace with your projections about the growth in the number of claims and services that you expect Medicare to provide next year, nor the growing complexity of the program.

Question. Is it your position as Administrator of Medicare while the program is growing by double-digit that a flat administrative budget is adequate?

Answer. Our administrative budget has increased about 7 percent from FY 1990 to FY 1991. We realize this is a modest increase given the increase in beneficiaries and program complexity. However, we have the responsibility to be as prudent as possible with our expenditures while operating the program as efficiently and equitably as possible. We believe our FY 1991 submission balances our program requirements with the need to meet deficit reduction targets.

Question. Doesn't this mean that we are going to sacrifice either proper control of Medicare spending or adequate service to the elderly, or both?

Answer. No. We believe this budget request will both provide proper spending control and adequate service to our beneficiaries.

OVERALL FUNDING SITUATION FOR MEDICARE CONTRACTOR ACTIVITIES

Our conference report directed that total Medicare contractor operations be continued at current services levels using funds that would no longer be needed to implement the catastrophic program.

Question. Have you followed this direction?

Answer. Restoring funds to Medicare contractor operations was a priority in realigning funds not needed for CHI. $114 million was used to augment payment safeguard funding and restore it to a level approximating FY 1989. In addition, $25 million was retained in contractors for the Catastrophic phase down activities.

Question. How do you explain the fact that your total fiscal 1990 funding level for these activities is $84 million below the amount that we appropriated, well beyond any cuts required for Gramm-Rudman sequester purposes?

Answer. The FY 1990 budget request was the result of negotiations between HCFA, HHS and OMB. The appropriated level was the result of Congressional action and the resulting reductions such rural referral centers, the drug war and Gramm-Rudman. Further, the HCFA operating level reflects the transfer of $45 million to SSA for catastrophic activities. We believe the funding level is adequate to operate the Medicare contractor program in an acceptable manner.

Question. Why were funds not released from the $100 million contingency fund which we appropriated so that unnecessary cuts could have been avoided?

Answer. The contingency fund was appropriated for expenses related to unanticipated workload. To date the only unanticipated workload which has materialized is the implementation of OBRA 89. Later in the year we may find it necessary to request some portion of the contingency.

Question. I would like you to provide us with a detailed breakdown of the differences between the amount that we appropriated and your current operating plan for contractor operations in fiscal 1990.

Answer. For contractor operations, the FY 1990 President's Budget contained $228 million for CHI. The appropriation was at the request level, however, with the repeal of CHI, we were able to redirect the $228 million. Most notable in the redirection was the reinstatement of payment safeguards funds as well as the ability to absorb legislatively mandated reductions and sequestration. Accordingly, our operating plan for 1990 is substantially below the appropriation level. The schedule below illustrates:

	FY 1990 Approp.	FY 1990 Oper. Plan
Payment Safeguards	$229.3	$339.1
Productivity Invst.	57.2	64.0
Claims Processing	994.5	952.2
CHI Drugs	158.0	0.0
Total Operating Funds	$1,439.0	$1,355.3

The changes from the budget justification in the FT 1990 Operating Plan figures represent the movement of funds needed to phase out Catastrophic as well as implement OBRA 89.

PAYMENT SAFEGUARD ACTIVITIES -- FY 1990 FUNDING

Last year this subcommittee made it clear that we were deeply concerned about reductions you had proposed in Medicare's payment safeguard operations. These are the operations that prevent overpayments and misspending by Medicare. Because of our concern, our conference report directed you to maintain funding for payment safeguard activities at the previous year (fiscal 1989) level of effort. We directed you to use funds no longer needed due to the repeal of the catastrophic program for this purpose.

Question. However, is it not true that payment safeguard activities are now funded below the fiscal 1989 level?

Answer. It is true that the FY 1990 funding level is slightly below the 1989 level. However, the payment safeguard activities which are most productive are funded at levels equal to or higher than FY 1989.

Question. How do you justify this action?

Answer. We believe our payment safeguard funding level for FY 1990 provides adequate protection to program payments while also allowing us to meet our legislatively mandated responsibilities to process and pay claims.

Question. How can we restrain health care costs if you are not willing to provide necessary funding for the activities that prevent wasteful or unnecessary Medicare payments?

Answer. Payment safeguards are just one of numerous approaches we have to restraining the growth of health care costs. Physician payment reform, controls over laboratory and durable medical equipment increases and restraint on hospital cost increases are also important in our overall strategy of controlling the growth of health costs. We believe our payment safeguard funding level is adequate and balanced with other program requirements.

COINSURANCE FOR MEDICARE LAB COSTS

Beneficiaries pay 20 percent co-insurance for most Medicare services, but not lab tests. The Congressional Budget Office has estimated five-year savings of $2.9 billion would be achieved by requiring a 20 percent co-payment for Medicare laboratory services.

Question. How much of a hardship would be imposed on senior citizens if they had to pay 20 percent of Medicare lab tests?

Answer. Assuming an effective date of October 1, 1990, the yearly costs to persons receiving reimbursement are shown below:

FY 1991	FY 1992	FY 1993	FY 1994	FY 1995
$13.48	$24.22	$27.29	$30.78	$34.69

Question. Wouldn't unnecessary lab tests be reduced if Medicare enrollees had to pay part of the cost?

Answer. Unlike physician services and all other diagnostic tests, clinical diagnostic lab services are not subject to any beneficiary cost sharing. We suspect that this contributes to some overutilization of services; however, we cannot quantify the extent to which this occurs.

IMPACT OF MALPRACTICE COSTS ON MEDICAID SERVICES

From 1982 to 1987, the costs of malpractice insurance premiums paid by obstetricians increased 238 percent and there are widespread reports that low income women, some of whom are Medicaid recipients, have experienced a great deal of difficulty obtaining access to obstetrical care. Lack of access to care or delayed access to care has had devastating results: increasing infant mortality and unnecessary costs for expensive, high-tech neonatal care.

Question. What can you do to ensure that pregnant Medicaid recipients have access to appropriate and high quality health care?

Answer. As part of HCFA's maternal and infant health initiative, our regional offices are helping States address the range of concerns expressed by obstetrical providers: low reimbursement levels and slow payment; paperwork and uncertainty about a woman's continued eligibility; and professional liability exposures and insurance rates. We face a major issue, that at the very time that Medicaid eligibility and coverage for lowincome pregnant women is expanding, the nation's obstetrical resources (obstetricians and family physicians doing obstetrics) are declining.

In a guide published last October, ***Medicaid Strategies to Save Lives and Money***, HCFA encouraged States to consider five approaches in addressing the issue: (l) raising fees and adding incentives to enhance physician participation in Medicaid prenatal care: (2) simplifying claims payment systems, and offering training and billing assistance to providers' staffs; (3) using an "ombudsman" approach to provider relations, improving program perceptions, including liaison with medical societies; (4) increasing the use of alternative providers, as certified nurse midwives, nurse practitioners, and clinics; and (5) enacting legislation to assist participating obstetricians in dealing with the high cost of liability insurance.

HCFA also executed a three-party agreement with the American College of Obstetricians and Gynecologists (ACOG) and the Bureau of Maternal and Child Health and Resources Development, Public Health Service, to help HCFA and State Medicaid agencies improve recruitment and retention of obstetric providers. Under this agreement, ACOG will address the whole range of issues and by the end of this fiscal year provide an effective practices guide for State Medicaid agencies, a guide for obstetricians on Medicaid participation and recipient needs, and help HCFA with technical assistance.

The Administration's effort to promote managed care in Medicaid can also provide substantial help in improving access for pregnant Medicaid recipients.

INAPPROPRIATE HOSPITAL ADMISSIONS

Nationwide, the PRO (Professional Review Organization) denial rate for inappropriate hospital admissions is less than 3 percent. Studies by other organizations, such as the SuperPRO, Rand Corporation, and others suggest that this number may be too low. In addition, a recent GAO report raises questions about the PRO methodology for detecting inappropriate admissions.

Question. Are the PROs doing an adequate job in detecting such admissions?

Answer. While SuperPRO data do show a higher number of inappropriate admissions, the Health Care Financing Administration does not feel that this is totally reflective of PRO performance. Many of the differences in the number of inappropriate admissions reported by the PROs and SuperPRO can be explained by:

- the requirement for the PROs to discuss the cases directly with the attending physician versus the SuperPRO evaluation based on review of case documents and PRO worksheets only; and
- disagreements which are based on knowledge of local practice patterns and local conditions, i.e., availability of facilities, personnel or equipment, which SuperPRO does not take into consideration.

HCFA takes the SuperPRO oversight activities seriously and uses the differences in the reporting of inappropriate admissions between SuperPRO and the PROs to provide further information for analysis of utilization problems and corresponding performance of the PROs. Under the third Scope of Work, HCFA is using SuperPRO findings as the basis for corrective action plans and other contract monitoring activities and, ultimately, renewal/nonrenewal decisions.

Question. Would increased preadmission review improve the ability of the PROs to reduce unnecessary hospital admissions?

Answer. Yes. Under the PRO third scope of work the number of surgeries subject to preadmission review was increased from 5 to 10 procedures. The PROs selected 8 of the procedures for preadmission/preprocedure review based on areawide data which indicated that intensified review would be effective (e.g., high denial rates) and result in reductions in unnecessary admissions. Additionally, HCFA requires all PROs to determine the medical necessity and appropriateness of setting for proposed cataract surgeries and carotid endarterectomies.

In addition, many PROs identify medical conditions (e.g., medical back problems and gastroenteritis) as utilization problems. Once identified, the PRO subjects elective admissions for these conditions to preadmission review.

As we analyze the review results, we will be able to evaluate the effectiveness of the review and change its focus as needed (e.g., expand review, change procedures reviewed, emphasize review of procedures that can be performed in a lesser setting, etc.). We also will evaluate the impact of increased preadmission review. For example, retrospective review (and identification of possible quality problems) would have to be reduced or the budget for the PRO program would have to be increased.

COST SAVINGS IN COMPUTERS

The cost-savings legislation I introduced last year would require Medicare contractors to share computer software and hardware, saving an estimated $100 million in administrative costs in the first three years after implementation. At last year's hearings, I urged that the Health Care Financing Administration go ahead to achieve greater efficiencies under existing legislative authority.

Question. Please give me a progress report on what you have been able to accomplish administratively regarding shared use of computer hardware and software.

Answer. Fifty-three contractors operate in some type of shared maintenance arrangement and twenty are involved in shared processing. It is HCFA's goal to have all contractors involved in shared maintenance or shared processing by the end of FY 1991.

Question. Do you still feel legislation is necessary in this area?

Answer. Yes. Although we have made good progress in inducing contractors to enter into shared processing and maintenance arrangements through persuasion and budgetary control, we believe ultimately there will be a number of contractors who it will be impossible to persuade without the legislative authority to compel their participation.

GETTING PRIVATE HEALTH INSURANCE TO PAY BEFORE MEDICAID

Medicaid is supposed to pay for health care only if no other resources are available. Yet, States have reported difficulties in getting private insurers located outside the Medicaid recipients' home state to pay for covered health care.

Question. Do States currently have the legal authority to require liable insurers, located outside the recipients' home state, to pay?

Answer. No. A State can only control the insurers in its own State. It has no authority to control an insurer in another State.

Question. If not, what legislative remedies are needed to empower the states to carry out this Congressional intent?

Answer. Federal legislation is needed to require insurers to reimburse the Medicaid program for medical expenses incurred on behalf of recipients who have assigned their rights to the Medicaid State agency.

USER FEE FOR PROVIDERS OF MEDICARE/MEDICAID SERVICES

Your budget proposes forcing providers and suppliers of Medicaid and Medicare services to pay the costs of their Federal regulation.

Question. Are you asking the Appropriations Committee to make this legislative change?

Answer. Yes. Our appropriation request requires Congressional approval of our intent to:

- establish a revolving fund into which user fees are deposited to fund FY 1991 survey and certification activities;
- expand the current authority to assess user fees on laboratories, as

1988, to include Medicare and Medicaid providers and suppliers requesting program participation; and

- authorize the use of user fees collected from laboratories in FY 1990 to capitalize the entire Medicare/Medicaid survey and certification program in FY 1991.

Since the FY 1991 budget proposes no appropriated funds for the survey and certification program, activities planned for FY 1991 revolve around timely approval of these proposals.

Question. If this legislative change is not made, how much would have to be added to your 1991 budget request?

Answer. The FY 1991 President's Budget assumes timely approval of the proposed legislative change.

If, however, the Congress decides not to approve the proposed legislative change, the cost of certification and quality assurance would require $308,011,000 appropriation as follows:

- $113,457,000 in Grants to States for Medicaid;
- $155,100,000 in Trust Funds for Medicare State surveys;
- $8,336,000 in Budget Authority for contract support;
- $24,567,000 in Trust Funds for administrative support;
- $6,551,000 in Budget Authority for administrative support.

$308,011,000 TOTAL

Question. Have you analyzed the impact these "user fees" would have on the nursing home industry, non-accredited hospitals, home-health providers, and hospices?

Answer. The impact that the fees would have on nursing homes, hospitals, home health agencies and hospices is expected to be minimal.

HCFA pays these particular facility-types for the covered care they provide to Medicare and Medicaid beneficiaries by means of a yearly cost report. Currently included in the cost reporting process is the provision to claim certain fees (e.g., an accreditation fee to the Joint Commission on Accreditation of Health Care Organizations) as an allowable operating cost.

HCFA anticipates, then, that these facilities will report the fees in their cost reports as allowable costs.

Question. Wouldn't you expect these institutions to simply pass the user fee costs on to consumers?

Answer. HCFA believes that the user fee assessment will be an extremely small amount when compared to the amount of benefit payments each facility receives. It has also been determined that the fee is an allowable cost of doing business that would be included in each facility's annual cost report to HCFA.

Question. You recommend establishing a "revolving fund", where the user fees would be deposited, and utilized to cover your administrative costs for survey and certification work. Won't you need an initial appropriation to capitalize this revolving fund, so you can cover administrative costs while you're waiting for the fees to be collected?

Answer. The survey and certification activities planned for FY 1991 depend upon the timely consideration and approval of legislative proposals. Given these approvals, HCFA plans to begin assessing laboratories user fees in FY 1990, under existing statutory authority, and depositing the fees into the revolving fund. These collections should provide an adequate start for the entire Medicare and Medicaid survey and certification program beginning in FY 1991.

FISCAL INTERMEDIARIES AND CARRIERS

The Omnibus Budget Reconciliation Act of 1987 required Medicare fiscal intermediaries and carriers to delay payment of provider claims for a minimum of 14 days after receipt during fiscal 1989. This requirement expired September 30, 1989. In a December 11, 1989 *Federal Register* Notice, the Health Care Financing Administration has made permanent the 14 day claims retention requirement. However, the notice also waives the requirement for claims received during the balance of fiscal 1990. The effect of this waiver is to shift some fiscal 1991 costs back to fiscal 1990, while the permanent claims delay policy will shift other fiscal 1991 costs forward to fiscal 1992.

It has been estimated that the temporary waiver of the claims retention requirement could cost the Medicare trust funds as much as $100 million in lost interests income during fiscal 1990.

Question. Is this estimate accurate?

Answer. No. We plan to waive the floor only for the last quarter of the year. We believe the interest loss will be about $20 million.

Question. What is the purpose of this shift of outlays among budget years?

Answer. The repeal of the Catastrophic program provided funds for numerous activities not originally funded in FY 1990. One of the activities we chose to provide funds for was suspending the 14 day floor and speeding up claims processing in the last quarter of FY 1990. This will result in more administrative and program expenditures in FY 1990 and less in FY 1991. This change will assist us in meeting FY 1991 Gramm-Rudman-Hollings spending targets.

ACCESS TO NURSING HOMES FOR MEDICAID BENEFICIARIES

Once an individual has been admitted as a private pay resident to a nursing home participating in the Medicaid program, that individual cannot be discharged from the home due to the subsequent inability to pay for nursing home care, that is after spending down to eligibility for Medicaid. The same nursing home, however, even though it voluntarily participates in the Medicaid program, can choose not to admit an individual who is already a Medicaid recipient at the time of application, even if the home has available space.

Question. Do you believe that the Congress intended that a program to provide health care to the poor would do so in a way that gives greater access to nursing home care to those who initially do not even qualify for Medicaid eligibility?

Answer. Yes, that appears to be the case based on the requirements in the law. Generally, the law allows qualified providers to undertake to provide care on a case-by-case basis. However, the Medicaid statute specifically prohibits nursing homes from transferring or discharging an individual who was admitted as a private pay patient and has become eligible for Medicaid. The law does not preclude States from imposing further restrictions on the provider's ability to pick and choose.

Question. Do you think there is a need to assure access to nursing homes for the poorest of the poor?

Answer. We believe that nursing homes typically are willing to accept individuals as Medicaid recipients. Nursing homes may not transfer or discharge an individual (on the basis that payment is made by the Medicaid program) who was admitted as a private pay patient and subsequently becomes eligible for Medicaid (section 1919(c)(2)(A)(v) of the Social Security Act). Since nursing homes may not transfer or discharge such individuals because of their subsequent Medicaid eligibility status, nursing homes typically are willing to accept the individuals as Medicaid recipients.

Question. Do you believe that the Federal government should require that Medicaid recipients be given equal access to nursing homes that volunteer to participate in the Medicaid program?

Answer. Like other qualified Medicaid providers, nursing homes should have a choice to furnish or not to furnish services to Medicaid recipients. Thus, a nursing home may refuse to admit an individual who is already a Medicaid recipient at the time of application, even if the home has available space. States may as a condition of licensure or otherwise require nursing homes to admit an individual who is already a Medicaid patient, when a nursing home bed is available. The Medicaid statute does not require qualified providers to furnish services to Medicaid recipients (section 1902(a)(23) of the Social Security Act.

Question. If so, what is your agency's position on the best way of assuring equal access?

Answer. It is appropriate for the Federal government and the States to assure equal access to nursing homes for Medicaid recipients. However, the Federal Medicaid program with cooperation from Medicaid State agencies appear to have already succeeded in generally assuring access to nursing home care.

CUTS IN MEDICARE CONTRACTOR FUNDING TO OFFEST RURAL REFERRAL HOSPITAL PAYMENTS

I understand that you have reduced the Medicare contractor funding level by $84 million below what we appropriated for fiscal year 1990. I am particularly concerned that a portion of these reductions included a $15 million cut to offset payments for rural referral hospitals. As a cosponsor of that provision, I made several specific statements last year that no funds from the Medicare contractor budget were to be used for the rural referral hospital provision.

Question. Why did you not follow our direction, and why were cuts made in the contractor budget for this purpose?

Answer. Reductions were made to HCFA's program management budget for rural referral hospitals, the drug war, and sequester. However, these cuts were made from funds that would have been used for the Catastrophic program. We believe the contractor budget is adequate to meet basic operational needs.

RESTRICTIONS ON PAYMENTS FOR SEAT LIFT CHAIRS

Last year, we discussed several recommendations of the Inspector General on restrictions that needed to be made in Medicare payments for certain services. For example, we proposed more rigorous review of payments for seat lift chairs and more aggressive efforts to prevent Medicare fraud.

Question. What actions have you taken to tighten up your practices for payment of seat lift chairs and generally to detect and prevent improper payment?

Answer. A Medicare Carriers Manual transmittal (#1284) was released to all carriers in December 1988, requiring supplier receipt of a signed physician order prior to delivery of a seat lift chair in accordance with the Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203, section 1834).

A HCFA-mandated payment screen requiring prepayment medical review of all seat lift chair claims was issued to all Medicare carriers in April 1989. Carriers received additional medical review funds to implement the screen.

A copy of the OIG report on Seat Lift Chairs (SLC's) was distributed to all Medicare carriers in June 1989 via Program Memorandum B-89-9. Carriers were asked to review the report carefully and to take appropriate action (*i.e.*, implement "best practices" identified by OIG) to deal with program vulnerabilities of the type cited in the report.

HCFA is developing in consultation with DME industry a medical certification form to be signed by the ordering physician. We intend to require use of this form on all seat lift claims.

STANDARD COMPUTER SYSTEMS

Question. What progress can be made in achieving greater uniformity in the computer systems used by Medicare contractors without disrupting accurate and timely payment of claims? Have you considered a realistic timetable for achieving this objective and have you included the additional funds required for this purpose in your budget request?

Answer. Currently there are twenty contractors operating in a shared processing environment. We continue to encourage this process and have budgeted $11 million dollars in FY 1991 for shared maintenance and processing activities.

LOST PAYMENT SAFEGUARD POSITIONS

Question. How many positions have been reduced in the operations of payment safeguard activities and in which areas?

Answer. Contractors have terminated 226 positions and reassigned 379 positions in the operations of payment safeguard activities as of October 2, 1989. The following chart details the number of positions terminated and reassigned in each payment safeguard area.

	MR	MSP	Audit
Terminations Part A	159	0	23
Terminations Part B	35	9	n/a
Reassignments Part A	98	1	11
Reassignments Part B	62	207	n/a

Combined Totals: 226 Terminations

379 Reassignments

Question. What are your proposals for restoring these positions so that adequate control over Medicare spending can be restored?

Answer. Adequate controls over Medicare spending is currently reflected in the funding levels of the FY 1991 Budget submission. The current level of payment safeguard funding provides for staffing which strikes a realistic balance between the need to protect program funds and meet legislatively mandated claims processing standards of timeliness and accuracy.

The level of payment safeguard funding, and the associated contractor staffing pattern, is consistent with HCFA's need to protect the integrity of program payments and its responsibility to process claims. The level of funding requested reflects a balance between the need to safeguard funds and the capacity of the contractors to efficiently absorb new work (such as physician payment reform and the IRS/SSA data match for Medicare Secondary Payer).

OVERPRICED DRUG FOR KIDNEY PATIENTS

According to Inspector General Kusserow, $544 million could be saved over five years as a result of estimating a reasonable charge for a new drug benefiting kidney patients eligible for Medicare. The Inspector General's semi-annual report states that the Health Care Financing Administration did not agree with its findings, and believed implementation could actually increase expenditures. (p. 35)

Question. Why do you disagree with the Inspector General's conclusions on this matter?

Answer. The OIG report in question refers to composite rate payments for dialysis rather than drugs. We did not agree with the OIG recommendation because we believe their proposal does not promote efficiency and may result in an increase in treatments by hospital renal facilities and thus escalate Medicare payments.

We did not agree with the OIG's recommendation to pay hospital renal facilities $36.75 more per treatment than independent renal facilities for a similar medical service. Paying hospital renal facilities substantially more for a dialysis treatment does not promote efficiency. Implementing the OIG's recommendation which is based on national audit data from 1984-1985 would promote the growth of hospital renal facilities. This would increase the number of treatments furnished by hospital renal facilities; and thus escalate Medicare expenditures. Since 1985, we have recommended reducing composite payment rates to reflect the costs of furnishing an outpatient dialysis treatment.

Question. Have you tried to resolve your differences of opinion on this issue?

Answer. On October 3, 1989, we met with the OIG to discuss their recommendation. In a memorandum dated December 5, we informed the OIG that we would submit an option paper to the new Administrator with one of the options being to use the 1984 and 1985 audited data. However, the age of the data is now a problem and would be an obstacle in any proposal to reduce the current composite payment rates.

Recent legislation, section 6203 (a)(1)(A) of the OBRA of 1989, prevents the Secretary from changing the base composite rates prior to October 1, 1990. In addition, before the end of the year, the Institute of Medicine (IOM) will publish its findings regarding the effects the composite payment rates have had on quality and access to care. The renal industry will expect the IOM's recommendations to be considered in any new rate proposal. We are in the process of conducting audits of renal facilities to determine the current Medicare costs of furnishing dialysis treatments. The audit results should be available at about the time the IOM study is published.

Regarding payment for the new drug epoetin (EPO) for renal patients, we are evaluating data from our contractors on this issue and will make any necessary adjustments to the payment rate following completion of this review.

POOR CHILDREN NOT COVERED BY MEDICAID

A recent report by the National Association of Hospitals alleges that only half of all needy child are covered by the Medicaid program.

Question. What is your assessment of the adequacy of Medicaid coverage of poor children?

Answer. Medicaid coverage was originally designed to provide medical assistance to the neediest and most vulnerable individuals in our population. As such, it was tied to eligibility requirements for programs providing cash assistance to certain groups of individuals living in poverty (as defined on a State-by-State basis). In recent years, legislation has been enacted to move away from these strict eligibility standards and mandate broader Medicaid coverage, particularly for pregnant women and children. We believe recently enacted Medicaid expansions will considerably improve the health care coverage our nation's children.

Medicaid now covers 13.3 million infants and children ages 1-20. Beginning April 1, 1990 one million more children will be covered by Medicaid as a result of recently enacted legislation (OBRA 89). Under this mandate, Medicaid will cover pregnant women and children up to age 6 in families with incomes up to 133 percent of the Federal poverty level.

Other recently enacted provisions concerning the Medicaid Early and Periodic Screening, Diagnosis and Treatment program and the Maternal and Child Health program will further increase the enrollment of pregnant women, infants, and children in Medicaid.

We will also be conducting demonstration projects to allow States to extend Medicaid to pregnant women and children not otherwise qualified to receive benefits. The projects will study the effect on access to health care, private insurance coverage, and costs of health care when States are allowed to extend Medicaid benefits.

Finally, the Family Support Act of 1988 extends the Medicaid coverage period for recipients of Aid to Families with Dependent Children (AFDC) for up to 12 months after losing their AFDC eligibility and requires Medicaid to be provided to two-parent AFDC families for up to 12 months.

Question. How many children in America go without even the rudimentary health care?

Answer. According to the March 1988 Current Population Survey, approximately 8.4 million children under the age of 18 have no health insurance coverage. However, lack of insurance coverage does not necessarily imply a lack of access to necessary health care. Community health centers and other sources of care are available.

Question. What would it cost to expand Medicaid coverage to the nation's impoverished children?

Answer. HCFA estimates that it would cost approximately $1 billion in additional Federal matching funds to provide Medicaid coverage to all children under the age of 18 whose family incomes are below the poverty line.

HCFA'S COMMON WORKING FILE

Federal guidelines recommend that an agency developing an automated information system conduct specific studies to ensure that the project is successful. These studies are to consider alternatives, obtain user input, and perform a risk assessment. Despite this guidance, your agency did not prepare the recommended documentation as the Common Working File (CWF) progressed. Latest estimates indicate that CWF will cost about $106.7 million through fiscal year 1991 to develop and implement.

Question. Why haven't you followed recommended federal guidelines and procedures in initiating and developing a Common Working File?

Answer. The Common Working File (CWF) is a contractor claims processing system, not a Federal automated information system. Further, the HHS Information Resources Management (IRM) Manual states that the material presented on Life Cycle Management is a guideline for systems development and may not be applicable to all acquisitions. For CWF, the circumstances clearly did not require the IRM process foreseen by the guidelines as HCFA transported an established system from a centralized to a distributed environment, while incorporating certain functional upgrades.

POOR FINANCIAL MANAGEMENT

GAO has called for government-wide improvements in financial management systems. There are reportedly billions of dollars of differences between balances recorded in accounting systems and financial reports.

Question. What is your assessment of weaknesses in financial management of your agency?

Answer. The weaknesses in financial management at the Department of Health and Human Services can be directly attributed to the antiquated financial systems currently in place. These systems are labor-intensive, relying heavily on manual processing and report preparation. Also, they are not properly linked to one another (e.g., procurement and core accounting). These deficiencies have led directly to the reconciliation problems recently reported by GAO.

Question. What specific areas could be strengthened, and what is your plan for making improvements?

Answer. Improvement of financial management systems is a major HHS initiative. The Department is implementing the Phoenix Project, which is aimed at strengthening HHS financial management systems by:

- continuing to improve and standardize budget and financial information systems and processes for greater operating efficiencies and control;
- consolidating financial information into an agency-wide perspective as required by OMB Circular A-127;
- implementing the Standard General Ledger system in HHS;
- modernizing our automated financial management systems and those administrative management functions which provide data to Financial Management; and
- further improving compliance with OMB/GAO requirements and the Federal Managers' Financial Integrity Act.

The HHS plan addresses the need for the timely implementation of actions to address these priorities as they affect automated systems, whether wholly within the Phoenix structure (e.g., the Operating Divisions' Accounting System) or interfacing with it (e.g., the Personnel Payroll System).

The basic concept for the Phoenix Project derived from the Federal government's Reform '88 initiative, which sought to reduce inefficiencies in the operation of governmental administrative and financial systems, and to promote improved decision-making, accountability, and system integrity controls.

Question. Do you agree with GAO's assessment that managers need more and better training in Financial Integrity Act issues?

Answer. The Department agrees that training is a key element in implementing an effective FMFIA program. In this respect, the Chairman of the Council on Management Oversight has already requested HHS' Assistant Secretary for Personnel Administration to develop a comprehensive, Department-wide FMFIA training program. In addition, the Director of the Department's FMFIA Program has been working with the Office for Civil Rights and the Family Support Administration in a separate effort to train their staffs under the auspices of the Office of Personnel Management.

NEW MEDICARE FEE SCHEDULE FOR DOCTOR'S SERVICES

Over the next several years, a new Medicare fee schedule covering 7,000 physician services and procedures will be phased in, cutting fees to specialists such as surgeons and radiologists, and raising fees paid to family practitioners.

Question. Do you expect this new system to simply redistribute Medicare outlays, or will it restrain overall expenditure growth?

Answer. For the most part, we expect implementation of the fee schedule to result in a budget neutral redistribution of payments for physician services. It is possible that changes in expenditures could result from changes in physician behavior as a result of the revised payment amounts.

To encourage physicians to eliminate unnecessary and ineffective services, physician payment reform legislation also contains Medicare volume performance standards (MVPS). The MVPS represents an acceptable amount of increase in Medicare expenditures for a fiscal year. It is not an expenditure limit. The MVPS will be compared with subsequent actual increases in program expenditures to partially determine the increase in physician payments for a subsequent year.

Question. What's to keep specialists from making up the loss of Medicare income by charging more for patient services covered under private health insurance?

Answer. While some physicians may charge non-Medicare patients more to make up reduced Medicare revenues, there are market factors that we expect to restrain the extent to which this happens:

Other third-party payors--particularly employer sponsored plans and Medicaid--will certainly resist raising their payments to make up for any reduction in Medicare.

Some third-party payors may eventually follow Medicare in the RBRVS which will lessen the opportunity to cost-shift.

MEDICARE OMBUDSMEN

Senate report language accompanying the fiscal 1990 Labor HHS appropriations bill called for demonstration projects at local Social Security offices, providing Medicare ombudsman services.

Question. What is being done to implement this report language?

Answer. HCFA has a Medicare coordinator project in all 50 States. For the past three years HCFA has worked with the appropriate SSA field operations staff in the development and execution of a training program for Medicare coordinators in virtually all SSA district offices.

UNNECESSARY ASSISTANT SURGERY SERVICES

Inspector General Kusserow estimated $312 million in savings from elimination of unnecessary assistant surgery services billed to Medicare.

Question. Do you agree with this assessment?

Answer. The Office of the Actuary at HCFA has estimated that eliminating all payments made for assistants-at-surgery would yield approximately $120 million in savings during FY 1991.

Question. What has been done to curtail unnecessary Medicare payments for assistant surgery services?

Answer. Laws and regulations governing the program have been strengthened with the carriers and PROs now providing greater oversight over the need for and use of assistant surgeons. Assistants at cataract surgery are not paid unless prior approval is obtained for complicated medical conditions. Manuals were also amended to prohibit payment to assistants when such use was found medically unnecessary. In addition, the Administration is proposing to modify payments for assistants-at-surgery with estimated savings in FY 1991 of $120 million, with a five-year savings of $880 million.

(Background: These savings are listed as already accomplished, on page A-1 of latest Semi-annual Inspector General report.)

MANAGED CARE

Question. Describe your proposals to reduce Medicaid and Medicare costs through "managed care."

Answer. We believe that managed care is preferable to fee-for service because it brings coherence to the delivery of health care. It emphasizes primary and preventive care and has the potential for providing improved health care at lower cost. Provided below is a detailed description of the managed care proposals.

MEDICAID

The President's FY 1991 budget seeks to increase the use of managed care in the Medicaid program through a three-part legislative initiative:

Financial Incentives: Beginning in FY 1991, States would receive a three percentage point bonus in their Federal matching rates for expenditures associated with increased managed care enrollment. Beginning in 1993, all managed care expenditures would receive the three percentage point bonus.

Also beginning in 1993, the matching rate paid to States for expenditures under for-service delivery systems would be reduced slightly, in order to just offset the cost of higher matching rates paid for managed care on a national basis. An additional limitation is that the decrease in the fee-for-service matching rate could not exceed 1 percentage point in 1993, 2 percentage points in 1994, and 3 percentage points in 1995 and beyond. On a national basis the reduction will be the lesser of the amount needed to just offset the cost or the specified annual percentage. On a State-specific basis there would be some States that receive an increase in Federal funds and some that would experience a reduction. Exceptions would be made for rural and medically underserved areas and for institutionalized individuals.

State Plan Option: Managed care would become a standard option for State Medicaid programs. States would be allowed to require recipient enrollment in approved managed care programs as a State plan option without having to apply for freedom-of-choice waivers. Periodic quality reviews would be required.

Enrollment Rules: Restrictions that impede HMO participation in Medicaid would be eased. Publicly operated HMOs and HMOs in medically underserved areas would receive a one-year waiver of the requirement that they have non-Medicare/Medicaid enrollment of at least 25 percent in order to enroll Medicaid recipients. Exemptions could be renewed indefinitely if annual, independent quality reviews show that the HMOs provide high quality care.

A one-month continuation of HMO benefits would also be allowed when Medicaid eligibility is lost. Existing State options to guarantee eligibility and restrict voluntary disenrollment of HMO plan members would be expanded. Recipients would still be able to disenroll with cause, and effective recipient grievance procedures would continue to be required.

States would be allowed the option (a) to require that each Medicaid beneficiary must make a choice between fee-for-service care and managed care, and (b) for any beneficiary who does not make a choice, to require the person to join a managed care plan while safeguarding, in part, their right to disenroll.

MEDICARE

Medicare Plus: Medicare Plus would encourage new Medigap policies that foster managed care through the use of preferred provider organizations (PPOs). Medicare beneficiaries enrolling could expect Medigap coverage for a reduced premium compared to standard Medigap policies. Medicare Plus enrollees would be required to use the PPO network in order to receive Medigap coverage.

The Medigap/PPO plan would be required to cover coinsurance and deductible payments for services provided within the PPO network. However, for services obtained outside the PPO network, the Medigap insurer generally would not cover any deductible or coinsurance charges.

These Medigap plans would be subject to State regulation and approval, and current minimum State requirements for Medigap insurance plans would have to be altered to permit marketing of these new products.

Medicare Plus would be in keeping with the trend in employer coverage toward managed care and PPOs. This proposal would allow insurers to use networks developed for their employer group business in their private Medigap line.

Payments to HMOs and CMPs: Payments to HMOs or competitive medical plans (CMPs) which enter into Medicare risk-sharing contracts would be increased to 100 percent of the amount paid for fee-for-service in their area--the Adjusted Average Per Capita Cost (AAPCC). A portion of this increase would go to the Medicare enrollees through a partial rebate of the Part B premium. The remainder of the increase would be provided to plans and would allow them to expand their current benefits or to make reductions in the premiums that enrollees pay in lieu of traditional Medicare deductibles and coinsurance.

Increasing the payment level from 95 percent to 100 percent of AAPCC will increase the availability of managed care options for beneficiaries, which will have a positive impact on the quality and cost of their medical care.

Question. How would reduced Medicare beneficiary premiums be paid for, to subsidize those who enroll in risk-contracted HMOs?

Answer. Increasing the HMO payments from 95 to 100 percent of the AAPCC will provide HMOs and CMPs with the resources to provide beneficiaries with a partial rebate of part B premiums in an amount equal to 5 percent of the lowest AAPCC in the nation.

SAVINGS RETURNS

Question. Last year you told us that you have achieved hard savings of about $9 for every $1 invested in payment safeguard activities of Medicare. What are your projections for fiscal 1991 and can you give us your savings return projections for each of the different payment safeguard categories?

Answer. We expect the overall payment safeguard return ratio to be about 11:1 in FY 1991. Medical Review is 6:1, Medicare Secondary Payer 38:1, and Provider Audit 6:1.

OPTIMAL CLAIMS PROCESSING COSTS

Question. What is the status of a private sector study on the optimal costs of processing each type of claim while meeting the HCFA standards for timeliness and accuracy?

Answer. HCFA contracted with Technology Management Corporation (TMC) in the Fall of 1988 to study, by claim type, the optimal cost for processing Medicare claims.

TMC submitted its final Part B report in December 1989; The Part A draft report is due in March 1990.

TMC's final report for Part B was developed after their visits to each of the 48 carriers and generation of a detailed report for each site. The individual site reports were used to develop a national data base. TMC then determined ranges of optimal costs by claim type for each contractor.

HCFA is now in the process of reviewing and analyzing the results of the Part B report. We are also developing various options which may be used in determining the funding for Part B carriers in FY 1991.

We do not have any information available for the Part A study since the draft report is not due until March 1990. HCFA expects to use the data from the complete report (Part A and Part B) when developing the FY 1992 budget.

Question. Can you tell us what is the lowest unit cost that can be paid?

Answer. HCFA has not yet determined the lowest unit costs by claim type.

HEARINGS AND RECONSIDERATIONS

Question. How well are the contractors able to handle hearings and reconsiderations at this point? Are they meeting the statutory requirements relating to timeliness?

Answer. Intermediaries are processing 97.5 percent of their reconsideration workload in 60 days compared to the requirement of 75 percent in 60 days. Carriers are processing 87.4 percent of their workload in 120 days compared to a goal of 90 percent in 120 days.

Question. How will the fiscal 1991 budget affect these activities?

Answer. The $57.5 million FY 1991 request for reconsiderations and hearings is $6.7 million less than the FY 1990 budget of $64.2 million. During FY 1989, HCFA implemented new procedures aimed at streamlining the appeals process to reduce administrative costs and processing time.

In particular, the following major changes were effected for carrier appeals operations, which account for over 87 percent of the hearings/reconsiderations workload:

- The use of simplified, shorter decision letters;
- Expanded use of on-the-record decisions; and
- Restricted use of reopenings, formal and informal.

We anticipate that the efficiencies achieved through implementation of these changes to the hearings and reconsiderations procedures will effect a higher level of consistency among contractors, enhance national uniformity, and permit contractors to render decisions of higher quality within statutory timeframes.

PHYSICIAN PAYMENT REFORM

Question. Is there any money in the budget for contractors to implement physician payment reform?

Answer. The FY 1991 budget contains $34.2 for physician payment reform.

HCFA was able to partially fund the OBRA 89 provision for physician payment reform from operating funds. However the majority of the $34.2 million for physician payment reform will be funded from the "Outlayed" contingency fund of $36.5 million.

Question. If so, where is the money going to come from? The contingency fund? A supplemental request?

Answer. The $34.2 million needed to fund physician payment reform in FY 1991 will come from operating funds and the "Outlayed" contingency. A supplemental request is not currently projected for physician payment reform. The majority of the funding will be from the "Outlayed" contingency while another substantial amount will come from the operating funds. We will assess our need for additional funds and the possible additional use of the contingency fund at a later date.

Question. If not, how are the contractors supposed to handle these new responsibilities?

Answer. As mentioned earlier, HCFA will assess its position with regard to the need for additional contingency funds closer to the time they may be needed.

CONTRACTOR PERFORMANCE

Question. What were the results of the contractor performance evaluation system for fiscal 1989?

Answer. The performance of the Medicare contracting community as a whole was very good. The FY 1989 Contractor Performance Evaluation Program (CPEP) measured the performance of all the Medicare contractors with respect to prospectively established criteria and standards. The contractors were striving to achieve the maximum available score of 1,000 points. The Medicare intermediaries attained an average of 97 percent of the available points. The Medicare carriers attained an average of 92 percent of the available points.

Question. Are any changes being made in the system?

Answer. The annual Contractor Performance Evaluation Program (CPEP) is working well and reflects the interests of all involved parties. A major systematic change was made in the CPEP and implemented for fiscal year 1988. Consequently no major changes are being made to the CPEP.

As a result of the ongoing assessment of the CPEP, certain minimum acceptable performance levels (APL) are being revised. Based on past performance it is clear that the contractors have surpassed our expectations in some instances. For those CPEP standards the minimum APLs are being revised upward.

Also as part of the routine annual assessment of CPEP, some standards are being added or deleted from the CPEP as appropriate to reflect changes in contractors' operating environments.

Question. If so, why? And if so, when will this revised system go into effect, and what effects is it likely to produce?

Answer. No major changes are being made. Some acceptable performance levels are being adjusted upward. Certain standards are being added or deleted.

MEDICARE CONTRACTORS' RESPONSIBILITIES

Question. Under the fiscal year 1990 budget, are contractors able to meet the statutory floors and ceilings for claims/bill payments?

Answer. Funding for FY 1990 is sufficient for all contractors to meet the statutorily mandated ceilings.

Part A contractors are successfully meeting agency requirements for processing clean non-PIP bills in 24 days. In January 1990 the national average for these types of bills was 98.6 percent. The standard is 95 percent. Part B carriers are having difficulty meeting the 17-Day CPT requirement for participating physician claims. In fact, an average of 20 carriers have failed to process 95 percent of their participating physician claims timely each month since October for FY 1990. In January 1990, the national average for the 17 day standard was 92.0. Nationally, carriers processed 95.7 percent of clean other than participating physician claims in 24 days.

Question. How are they likely to fare under the fiscal 1991 budget request?)

Answer. Funding for FY 1991 is sufficient to allow contractors to meet all requirements based on our projections for processed workloads.

Question. What about for the participating physicians programs?

Answer. The narrow payment window for Participating Physicians will continue to be a problem unless relief is given as outlined in our legislative proposal to raise the ceiling to 21 days.

Presently, claims for participating physicians are processed in a 3-day "window" between the 14-day payment floor and a 17-day ceiling. Over weekends, only one working day is available and when holiday weekends are considered, this 3-day window can not be met without overtime. Such a narrow window for paying claims is unrealistic and unworkable given the hundreds of million of claims processed annually, hence carriers cannot always meet the 17-day payment standard. We hope to rectify this situation through a legislative proposal.

PEER REVIEW ORGANIZATIONS

Question. What is the status of the demonstration project in which Professional Review Organizations (PROS) are to review care delivered in physicians' offices?

Answer. On December 1, 1989, the Health Care Financing Administration's contract with the Wisconsin Peer Review Organization to review care in physician offices began. The pilot project also includes the Peer Review Organizations for Arizona, Utah, Indiana, Connecticut, North Carolina, and Washington.

Over the first two months of the project, panels of physicians developed lists of data elements pertaining to the sixteen medical conditions for which data will be abstracted from physician office records. Eventually, data for about 43,000 patients under treatment by six hundred physicians will be reviewed. The pilot project is scheduled to last for two years.

A recent decision by the 9th Circuit Court of Appeals in California (Citizen's Action League vs. Kizer and Sullivan) limits the ability of that state to recover from the estate of a Medicaid recipient in cases of joint tenancy. The decision centers around the term "estate" and the absence of a definition in the law or regulation. The court ruled that property that passes by right of survivorship--thereby bypassing probate--is not covered under the estate recovery provisions. In a 1986 letter, then HCFA Administrator Roper agreed that California's interpretation of the law was reasonable.

Question. Does HCFA plan to support California in an appeal of the Circuit Court of Appeals decision? If not, why?

Answer. HCFA continues to support California's position that the term "estate" is broader than the court's interpretation which limited it to the "probate estate". We have recommended that the Circuit Court of Appeal's decision not be appealed because of a procedural matter.

On September 4, 1986, HCFA issued a policy statement to California in support of its position that the term "estate" is not limited to the probate estate. HCFA continues to support the State on this policy matter. Based on advice furnished by the Office of the General Counsel, we do not believe that there were grounds for a rehearing or a writ of *certiorari* under the applicable procedural rules. Pursuant to Rule 40 of the Federal Rules of Appellate Procedure a petition for rehearing should only be made to direct the Court's attention to a material point of fact or law overlooked in the decision, a change in the law which occurred after the case was submitted, or an apparent conflict with another decision of the Court which was not addressed in the opinion. None of these criteria was present in this case.

Question. Why hasn't HCFA published regulations containing a definition of the term "estate?" Does HCFA plan to publish such regulations now? If so, will they permit recoveries in joint tenancy cases?

Answer. Most States already have in place a recoveries policy based on the broader interpretation of the term "estate". In light of this, HCFA is not intending to publish a regulation at this time. If we were to issue a notice of proposed rulemaking, we would propose to permit recoveries in joint tenancy cases.

Question. How prevalent are joint tenancy/right of survivorship provisions? What are the implications of the California decision on recovery programs in other States?

Answer. Most States have such provisions. In every such State with an active recovery program, savings could drop by as much as 33 percent (based on California's estimate) if this ruling stands.

Question. Are joint tenancy/right of survivorship Clauses likely to proliferate if this loophole is not closed? Would you support federal legislation?

Answer. Yes, if joint tenancy/right of survivorship clauses are not closed we anticipate they are likely to proliferate. This is an issue that merits futher consideration.

FREESTANDING PROVIDERS

More and more care that traditionally would have been provided in hospitals that must meet strict quality assurance requirements and are licensed by the States is being provided by freestanding providers.

Question. Is it appropriate for the federal government to pay for care through facilities that are not even required to be licensed by the State in which they are located?

Answer. This is a difficult question to answer mainly because of the way it has been posed.

It is certainly appropriate and necessary for the States and the Federal government to impose health and safety standards on providers of health care. One of the enduring achievements of the Medicare program has been its support for strong and effective State licensure efforts through its conditions of participation. Today we have long passed the era in which basic health and safety regulation is the necessity and have moved into an era where the challenge is to deal with the increasing proliferation of specialized providers in a rational way.

To answer the basic question you ask about payment for care provided in settings for which there is no State licensure requires an examination of the relative roles of the States and the Federal government. We generally require that facilities meet all applicable State and local licensure laws. However, it is up to States to determine what types of facilities are subject to licensure requirements, and what those requirements will be. It is outside the Federal scope of authority to require that States license particular types of facilities.

THIRD-PARTY PAYMENTS

States are required to seek recovery from liable third-parties within specified time frames.

Question. Do you believe that liable third-parties should likewise be required to make payment within similarly specified time frames?

Answer. Yes. It would make it easier to make recoveries.

GAO REPORT ON MEDICAID PAYMENTS

In its February 1985 report *Improved Efforts Needed to Relieve Medicaid from Paying for Services Covered by Private Insurers* (GAO/HRD-85-10), the General Accounting Office recommended one of two options to improve State practices for identifying and using Medicaid recipients' insurance resources. These options involved strengthening HCFA's regulatory requirements and compliance reviews of State programs or using its quality control program to determine the amount of erroneous payments attributable to unrecovered health and casualty insurance and denying federal sharing in such erroneous payments exceeding a specified level of performance.

Question. What action has HCFA taken in response to the GAO recommendation?

Answer. HCFA has taken a number of actions to improve third party liability (TPL) recoveries.

First, several regulations have been issued since February 1985 to strengthen requirements in this area. Provided below are summaries of these regulations. The dates on which they were published in the Federal Register are indicated in parentheses.

- State Medicaid agencies must use the cost avoidance method of claims payment where the probable existence of TPL exists at the time a claim is submitted by a provider (November 12, 1985);

- State Medicaid agencies must:

  + obtain health insurance information for Medicaid applicants or recipients during the initial application or redetermination process;

  + conduct data exchanges with specific State and Federal agencies or, in some cases, alternate sources to identify legally liable third parties; and

  + conduct diagnosis and trauma code edits to identify third party resources. (February 27, 1987)

- State Medicaid agencies must follow certain protocols regarding:

  + integration of a State's pursuit of third party claims with its mechanized claims processing and information retrieval system;

  + exceptions to the cost avoidance method of claims payment in certain situations; and

  + provider restrictions and penalties related to attempts at collection of cost sharing from Medicaid recipients when TPL has been established. (January 16, 1990)

Secondly, in addition to the issuance of regulatory requirements, a number of administrative actions have been taken. HCFA has:

- developed a review protocol for monitoring State implementation of TPL regulations; reviewed all States for compliance with the TPL regulations; and ensured that corrective actions were taken where necessary;

- published a "Guide To Successful State Agency Practices" (a compilation of State TPL practices proven to be cost-effective);

- conducted joint reviews with the Office of Child Support Enforcement to determine if medical support regulations are being enforced;

- entered into an agreement with the Department of Defense for Medicaid agencies to conduct data matches to identify Medicaid eligibles who are also eligible for military health care benefits and the Civilian Health and Medical Program of the Uniformed Services;

- conducted TPL conferences nationwide, several in conjunction with the American Public Welfare Association;
- developed a State specific marketing program to promote TPL recovery programs in States which have not fully developed their potential;
- awarded a contract to develop a methodology for measuring cost avoidance savings and to determine the amount of untapped TPL,
- made TPL presentations to national health organizations and associations, including the National Conference of State Legislatures and the National Association of Insurance Commissioners; and
- assisted States in pursuing recovery cases where there is a need for national intervention.

HCFA is also developing a national TPL data base.

MENTAL HEALTH SERVICES AVAILABLE UNDER MEDICAID

Because States determine, within broad federal guidelines, what benefits will be provided as well as what limitations will be placed on benefits available to Medicaid recipients, wide variations have developed over the years for Medicaid benefits in general and mental health benefits in particular.

Question. Does HCFA, through any of its information systems, gather standardized data on specific mental health benefits and their limitations in each of the States?

Answer. Yes. State Medicaid agencies submit each year aggregate statistical reports concerning various aspects of their State Medicaid programs. The number of recipients, expenditures and days of institutional care are reported in four categories that reflect mental health benefits. These categories are mental hospital services for the aged, SNF/ICF services for the aged in mental health facilities, inpatient psychiatric facility services for individuals age 21 and under, and intermediate care facility services for the mentally retarded. In addition to the aggregate statistics submitted by all States, almost half the State Medicaid agencies also submit individual claims data that reflect services received in these four categories. The latest statistical Medicaid data available is for federal fiscal year 1989.

HCFA has periodically surveyed the State Medicaid agencies to ascertain what optional services are covered by each State and what limits, if any, are imposed on those services. Since the four categories of mental health benefits listed above are optional coverage under Medicaid, HCFA has information about State Medicaid coverage and limits imposed for them. The latest survey information is contained in the HCFA Program Statistics publication Analysis of State Medicaid Program Characteristics, 1986.

Question. Does HCFA have a need for such data?

Answer. Yes. The statistical data and information collected from State Medicaid agencies are used by policy analysts, budget planners, actuaries and researchers to evaluate, monitor and manage the Medicaid program at the federal level. The data are used extensively by the Department of Health and Human Services, the Office of Management and Budget, congressional staffs, and other public and private enterprises in the health care community.

COMMON WORKING FILE MODIFICATIONS

HCFA is planning to make, or is in the process of making, software revisions and other modifications to CWF during fiscal years 1990 and 1991. Specific information on the cost of these modifications for fiscal year 1990 has not been available. The estimated cost of the fiscal year 1991 modifications is about $12.5 million, but may be adjusted. Although HCFA has provided cost estimates to develop and implement CWF, the costs may not represent HCFA's most current estimate.

Question. What is the projected life-cycle cost for CWF?

Answer. It is difficult to estimate the life cycle cost for CWF. We anticipate that, absent significant program changes, CWF will last a minimum of 10 years beyond the final implementation year of FY 1991. We would estimate at this time that the system's yearly operational and maintenance cost would be approximately $25 million in constant FY 1992 dollars. This, together with the estimate of about $100 million in total costs through FY 1991, yields a total life cycle cost for CWF of approximately $350 million.

Against this HCFA estimates administrative savings from elimination of certain current systems/claims processing activities of not less than $213 million in administrative costs and $1.315 billion in program savings.

Question. Does HCFA expect to request funds to modify CWF beyond fiscal year 1991? If so, please describe these modifications?

Answer. HCFA will request CWF funds after FY 1991. HCFA will seek to enhance function and use of the system through the incorporation of new technologies such as expert systems as the opportunities arise. Also, HCFA will seek out mechanisms to improve and extend program safeguard monitoring within CWF to reduce inappropriate program outlays.

Question. What would it cost to consolidate all contractor data processing functions into host sites? What are the benefits of such a consolidation?

Answer. HCFA has not studied the possible ramifications of contractor data processing consolidation using the CWF. We have no information available to us on operational problems, benefits or costs. CWF is not yet fully implemented and no such study is currently planned.

Question. If consolidation is cost-effective, what are HCFA's plans to further consolidate contractor data processing?

Answer. HCFA has no plans at present to consolidate contractor data processing operations into CWF. We use opportunities presented to us by contractors voluntarily leaving the Medicare Program to consolidate operations. In addition, we are conducting an initiative to identify opportunities for contractors to enter into shared processing arrangements voluntarily, and thereby reduce the Agency's overall claims processing costs. At present 20 contractors are in shared processing arrangements and three more are scheduled to join existing arrangements during FY 1991.

OVERSIGHT AND EVALUATION

Information systems development activities are typically reviewed and approved by an agency's senior official for information resources management to ensure that the projects fit in the agency's strategic plan. To support agency-wide ADP and telecommunications planning and acquisition, the senior official approves all acquisition of information resources.

Question. Has HCFA'S senior official reviewed the costs and benefits of CWF and what is the official assessment of CWF?

Answer. The CWF project was conceived, developed and implemented as a program operations project within the scope of the Medicare Contractor operations. HCFA has reviewed the costs and benefits of the Common Working File to assess the benefits that would accrue once full operational status is achieved beginning in CY 1991. HCFA has estimated that annual program savings of $125 million and annual administrative savings of $20 million would be realized as a result.

Question. What assurance does HCFA have that CWF will effectively support its overall ADP and telecommunications strategy?

Answer. CWF is consistent with the HCFA IRM strategy to encourage the collection and processing of data as close to the source as possible. The effort has been subject to continuing review by HCFA systems developers and the MITRE Corporation as part of the Project to Redesign Information Systems Management (PRISM). CWF involves decentralizing the processing of large data bases and streamlining the claims approval, payment, and audit mechanism so processing takes place in close relationship to the point of the claim.

All of these approaches are in close agreement with the best current industry standards and practices for efficient, effective automated claims processing. HCFA will continue close oversight of this critical process and ensure its integration into future IRM plans and efforts.

DEVELOPMENT OF COMMON WORKING FILE

Question. When developing CWF, how did HCFA:

- consider alternative systems;
- obtain input from potential users, such as carriers and intermediaries; and
- conduct a risk assessment of CWF?

Answer. No alternatives per se were considered. No commercial applications met the requirements of the unique HCFA claims processing environment. We had determined that the system must continue and improve upon the eligibility and utilization safeguards present in the old system, and the remote, on-line processing capability demonstrated in the SPIDER project, and bring together all Part A and Part B claims data and MSP information to support payment safeguards. Finally, to support the need in HCFA for timely data on program expenditures for program management, we added as a by-product the near real-time database in Baltimore. CWF is that system. No alternative can meet the requirements.

Input from contractors was not gathered formally for CWF. We did have more than 20 years of contractor interface problems with the query/reply system available for our use. In addition, we used the experience of Arizona Blue Cross under the SPIDER Project as part of our requirements analysis. Finally, we formed a joint development team with Maryland Blue Cross and Blue Shield, which is both an intermediary and a carrier, to conduct the final design and development work. Maryland drew extensively on its A and B claims staff as well as its systems staff for CWF. Thus we feel that user requirements were well developed, considered and incorporated into the final system.

A risk analysis as thought of under traditional IRM was not done. HCFA believed that the greater risk was to remain under the obsolescent query/reply system which was becoming increasingly hard to modify to meet Congressional program changes. For example, it would have taken approximately 6 months to develop, test and install the changes needed to support the return to spell of illness processing under Catastrophic repeal. CWF made the changes in approximately 2 months. Further, the old system did not provide HCFA with flexible mechanisms to enforce program requirements and forced us to operate in a pay-and-chase environment when contractors made errors. The conservative estimates for program and administrative savings outweighed potential risks. Further, by operating in a distributed mode, CWF eliminated the greatest operational risk under query/reply, single point of failure at the Baltimore processing site.

ALZHEIMER'S DISEASE MEDICARE DEMONSTRATION

In 1986, Congress authorized a three-year, $40 million, demonstration which would provide Medicare payment for home and community based long-term care services needed by Alzheimer's patients and families. We wanted information on the types of services these families need and the cost of those services.

I understand that there has been considerable delay in getting this demonstration started and that you have cut back on the original design. I am concerned now about whether we are going to learn what we need to know from these projects and want to ask you some questions about them.

Question. How much of the $40 million have you committed to date and can you break that down by project? Do you expect to spend the entire $40 million, and if not, why not?

Answer. In accordance with the legislative guidelines to conduct the project in at least five but not more than ten geographically-diverse sites, and after reviewing the proposals submitted, HCFA selected eight sites.

The original design of the demonstration included budget parameters that would permit up to ten sites to be funded within the $40 million cap. Because only eight sites were selected, HCFA has permitted these sites to increase their proposed client caseloads and, where justified, increase their budgets to recognize other appropriate costs. Budget information for the individual demonstration sites is attached. Based on these current budgets, the expected expenditure level is approximately $34.0 million. However, we retain the flexibility to increase the sites' budgets if current projections need to be adjusted at a later date.

MEDICARE ALZHEIMER'S DISEASE DEMONSTRATION SITE BUDGETS

SITE	APPROVED SITE BUDGET
Memphis, Tennessee	$3,470,367
Rochester, New York	3,479,299
Urbana, Illinois	2,785,907
Portland, Oregon	3,506,190
Cincinnati, Ohio	4,820,081
Parkersburg, West Virginia	2,642,792
Miami, Florida	6,270,546
St. Paul, Minnesota	6,784,386
SUBTOTAL	$33,759,568
TECHNICAL ASSISTANCE	$215,000
TOTAL	$33,974,568

ALZHEIMER'S DISEASE MEDICARE DEMONSTRATION

Question. I understand that the projects have only begun accepting participants in the last few months. Why did it take so long to get started and what impact is that having on participants? How long will services be provided and when will you have to start gearing down?

Answer. The development and implementation of an innovative large-scale initiative such as the Medicare Alzheimer's Disease Demonstration is a complex and lengthy effort. The time we invested initially in developing the project's research design and evaluation plan has contributed to a successful implementation.

In an effort to be responsive to the intent of the authorizing legislation, HCFA staff met with the staffs of several of the bill's congressional sponsors to clarify the intent of the legislation and expectations for the project. We then convened a panel of experts to help shape multiple aspects of the demonstration, to be sensitive to the needs of Alzheimer's patients and their families, and to build on other research and experience in the field. Next, HCFA awarded a contract to Mathematica Policy Research, Inc. to assist in development of the project's design and evaluation plan, and in soliciting and reviewing applications from potential demonstration sites. Before final site selection, HCFA staff visited the 19 top-ranked applicants to further assess their capabilities to contribute to an effective demonstration. With final site selection, in May 1989 sites began a 6-month operational development period to adapt and expand their physical facilities, hire staff, and conduct outreach campaigns to publicize the demonstration.

Concurrently, HCFA awarded a contract to the University of California, San Francisco to evaluate the demonstration and to provide technical assistance to the sites in client intake, assessment, and data collection. Upon HCFA approval of the sites' final operating protocols, service delivery began December 1, 1989.

Since the 3-year demonstration period specified in the original legislation began in May 1989, the provision of services under the demonstration is scheduled to end in May 1992. However, we expect to begin the process of gradually reducing the sites' client caseloads in December 1991. During that time, caregivers will be given information on alternative services available in their communities. The purpose of this wind-down phase is to ensure a smooth transition for all Alzheimer's patients and their families.

Question. Will the actual full service phase be long enough to get useful information, particularly for a disease that lasts as long as Alzheimer's?

Answer. This demonstration is not intended to study clinical aspects of the progression of Alzheimer's disease on its victims. Rather, the demonstration will assess the benefits and costs of providing home and community-based services to Alzheimer's victims and their family caregivers and provide information about what combinations of health and social support services are most cost-effective in promoting and prolonging home-based care for these patients and their caregivers. We expect the demonstration to include Alzheimer's victims at all stages of the disease. Consequently, we are confident that this demonstration will produce useful information within the timeframes established by Congress. Discussions with the project's evaluator (University of California, San Francisco) have indicated that the data collection phase of the demonstration is sufficient to determine the cost, effectiveness, and impact on health status and functioning of providing home and community-based services to Alzheimer's patients and their families. In order for the evaluator to study the effects of the demonstration over an adequate period of time, our implementation calls for the demonstration sites to achieve their client caseload targets by October 1990. If the sites are unable to achieve these caseload targets within that schedule, HCFA will reassess the implications for the evaluation.

MEDICARE INTERMEDIARIES AND CARRIERS

Fiscal Year 1990 Last year the Committee was very concerned that the $1.439 billion requested by the Administration for Medicare intermediary and carrier operations was insufficient to maintain adequate levels of claims processing and program payment safeguards. As it turned out, the repeal of the catastrophic health insurance benefit freed up funds within the requested amount that could be reallocated to strengthen regular claims payment and program safeguard activities, and Congress directed that it be done.

Question. Please provide the Committee a breakdown of the actual contractors' operations budget for fiscal year 1990, indicating how the catastrophic-related funds were reallocated.

Answer. Our current estimate for FY 1990 provides $339.1 for payment safeguards, $64.0 for productivity investments and $952.2 for claims processing. Catastrophic funds were used to restore payment safeguards to prior year levels ($114 million), transfer of funds to SSA for recalculation and programming of the premium ($45 million), the McClure and Byrd amendments ($47 million), phase down activities ($60 million), HCFA pay raise and sequester ($27 million).

Question. Fiscal Year 1991 We would also like to know how the proposed figures for fiscal year 1991 contractor claims payment and program safeguard activities compare with the current fiscal year allocation. Since, historically, Medicare claims have increased in number at a rate of about 10 percent or more annually, and both claims payments and safeguards relate directly to the number of claims to be processed, please include your assumptions with respect to the contractors' workload in each fiscal year.

Answer. Workload growth is an important variable in contractor budget requirements. However, factors such as increased mechanization and productivity restrain dollar growth to less than the rate of claims growth. In addition, we believe the rate of claims growth is moderating and will be lower in 1990 and 1991 than it has been historically. We expect to process 83.6 million Part A claims in 1990 and 82.4 million in 1991. For Part B we expect to process 463 million claims in 1990 and 465.1 in 1991.

Question. OBRA 1989 Finally, the Omnibus Budget Reconciliation Act of 1989 included extensive provisions dealing with physician payment reform under Medicare. Many of those changes will involve work by Medicare carriers in fiscal year 1991. Please indicate for the Committee how the cost of carriers implementing OBRA '89 changes is handled in the

FY 1991 proposed contractor operations appropriation, as opposed to the cost of ongoing contractor activities such as claims payments and program safeguards.

Answer. OBRA 89 will require funding for both developmental and operational activities. The FY 1991 budget contains a portion of these costs in the operational categories, however, we intend to fund the majority of OBRA 89 expenses from our contingency fund.

ALTERNATIVE DELIVERY MODELS

There has been a great deal of discussion about increasing efficiency in health care delivery. The Department has advocated that hospitals "downsize" to reduce their excess capacity. I know that my home state of Iowa and several other states are interested in trying to promote new models for delivering health care services, such as the Medical Assistance Facility model developed in Montana.

Question. Have any alternative model demonstrations been approved yet? Is HCFA funding any of these models? If not, why not -- where is the bottleneck?

[Background: The Iowa office of rural health recommended in a report to the Legislature Feb. 1st that the state not adopt alternative models for health care delivery because HCFA has not yet developed a mechanism for paying for Medicare and Medicaid services.]

Answer. ORD awarded a grant to the Montana Hospital Association to refine the design of the Medical Assistance Facility (MAF) project in September 1988. A MAF is a new health care facility providing low-intensity acute care services to short-term inpatients in frontier areas. The length of stay is limited to not longer than 96 hours.

The hospital association invited 24 hospitals to participate in the demonstration. To date, three hospitals have expressed interest in pursuing the demonstration in 1990, and HCFA is working with Montana to resolve payment and certification issues. The demonstration is scheduled to be implemented during this summer.

In addition, the Omnibus Budget Reconciliation Act of 1989 established the Essential Access Community Hospital/Rural Primary Care Hospital (EACH/PCH) Program. This program is designed to maintain access to cost-effective quality health care services in rural areas. The program provides a means for small rural hospitals to remain financially viable by converting to "rural primary care hospitals" (PCH) through the restructuring of their services to a less intensive level.

The EACH/PCH program is a major policy undertaking which requires extensive coordination and review of HCFA policies dealing with payment coverage and quality assurance. The program, which is intended to provide grant funds to as many as seven states and numerous individual hospitals, will be implemented in fiscal 1991, if funds are appropriated. OBRA 89 authorized $10 million for the EACH/PCH program; however, there is currently no appropriation available for this purpose. Should funding become available, the program would be evaluated so that the Secretary can incorporate findings from this program into recommendations to the Congress which are due April 1992.

Finally, for the past year, HCFA has conducted the Rural Hospital Transition Grants (RHTG) program. This program provides up to $50,000 per grant to small rural hospitals for the planning and implementation of projects to modify the type and extent of services that these hospitals provide. In the first year of the program, HCFA awarded $8.3 million in grant funds to 181 hospitals and consortia in 45 states. $17.8 million has been appropriated for the program during this fiscal year for second year funding of the original grants and approximately 185 new grants. HCFA has contracted with Mathematica Policy Research, Inc. of Princeton, New Jersey to monitor and evaluate this program.

UNFAIR VARIATION IN PHYSICIAN PAYMENT LEVELS

Under the current reimbursement system, HCFA pays doctors widely varying amounts for the same procedure, depending on geographic location. In implementing physician payment reform, mandated by the 1989 reconciliation legislation, the opportunity exits to even out these wide, unjustified disparities.

Question. What is being done, for example, to avoid perpetuating unfair geographic disparities in fees for radiology services?

Answer. The interim final regulation establishing the fee schedule for radiology services used the existing carrier locality structure in setting the payment amounts.

We received a number of comments on the regulation about using existing carrier localities and about the variation in payment between geographic areas. In addition, we have met with the American College of Radiology on this issue. One methodology which was discussed would use the concept of a geographic cost of practice index to calculate payment amounts in each carrier locality. We are currently studying this and other options.

Question. What is the time frame for implementing new schedules based on "relative value scales" called for in the new legislation?

[Background: Dr. Ruben Koehler, from Des Moines, brought this issue to the Committee's attention. He illustrates the problem by pointing out that HCFA pays 100 percent higher for radiology services in a small Illinois town as it does for Des Moines.]

Answer. A national fee schedule will be implemented gradually beginning FY 1992. Under this national fee schedule there will also be variations in payment between different areas. However, these differences will be based on the costs of operating a practice. Application of this index will substantially narrow the variations between areas. Preliminary data indicate that physicians in Iowa will do better under the new system.

CODING AND BILLING

Recently HCFA has been systematically reviewing the use of CPT service codes. This review requires extensive communication back and forth between the intermediary and physicians' offices, much paperwork, and frequently a delay in payment.

In addition, most physicians in the past used a relatively limited number of service codes. Medicare now requires a more extensive list of service codes. However, for the doctors who begin to use more service codes, reimbursement is extremely poor as by regulation Medicare sets a very low level of reimbursement for initial use of service codes where there is no previous charge experience. Physicians are therefore required to use a more extensive list of codes, with greater chance of error, and are put in the position of having reimbursement lowered by use of new codes.

Furthermore, HCFA now requires that diagnoses be coded to five digits. For instance, it is not longer sufficient to code as osteoarthritis, the code must be a five digit code to indicate that it is osteoarthritis of the knee, hip, or hands. This requires more paperwork and more time. It also introduces a greater chance of error. Although Medicare presumably requires this coding for its own purposes, if the coding is not done to their satisfaction the payment is delayed and Medicare may even refuse payment. If there are frequent errors in coding, Medicare may even charge physicians for fraud and abuse.

Question. What steps is the Department taking to increase payments for the additional time and personnel that must be devoted to administrative services?

Answer. The Department is not planning to make any adjustments in payments to reflect the administrative time that may be used in putting correct procedure and diagnosis codes on Medicare claims. Although diagnosis coding is now a statutory requirement, many physicians supplied this information even before the coding was mandatory. Moreover, under the physician payment reform provisions of the Omnibus Budget Reconciliation Act of 1989, it is expected that a resource based relative value system will adjust payment levels for various categories of physicians' services. We estimate that the payment levels for physicians' evaluation and management services (visits and consultations) will be increased when the new payment system goes into effect in 1992.

As a second issue, during the short time that the catastrophic health bill was in effect, Medicare recipients were permitted to be admitted directly to swingbed status without three days first in acute bed status. This was a very helpful regulation, as it allowed some patients, for example those who had severe back problems not responding to treatment at home, to be observed and treated more intensively than was possible as an outpatient, but yet without the cost and intensity of true inpatient admission. This should have saved money for Medicare also since swingbeds are less expensive than hospital inpatient service. Since admissions either to swingbed or to hospital are some what gray in these circumstances, it is likely the patients are being admitted to the hospital who could have been admitted to swingbed under the regulations.

Question. Is the Department considering reinstituting the waiver of requirement of three inpatient days before admission to swingbed?

Answer. We are not currently considering waiving the 3-day prior hospital stay requirement for admission to a hospital swing bed for SNF care.

Under Medicare, requirements that relate to coverage of SNF care in hospital swing beds are the same as the requirements that relate to SNF care provided in an SNF. While Medicare Catastrophic Coverage Act (MCCA) of 1988 was in effect, beneficiaries could be admitted directly to

SNFs and swing beds in order to receive covered SNF care. Now that MCCA has been repealed, however, the 3-day prior hospitalization requirement is reimposed in both settings.

The law does contain the authority for the Secretary to provide by regulation for coverage of SNF services without imposition of a 3-day qualifying stay; however, the law conditions the exercise of this authority on a finding that such a change would not result in an increase in total payments under Medicare or alter the character of the Medicare benefit.

We have not been able to exercise this authority because we do not believe that the 3-day qualifying stay could be eliminated without increasing Medicare payments.

While we are not currently considering exercising this authority, we are open to reviewing any additional data that may indicate that the statutory conditions for waiving this requirement can be satisfied. We do not, however, believe that such data is currently available.

COMMUNICATIONS BETWEEN HCFA COMPUTERS

Question. What does HCFA plan to do about unifying the communications between all of its computers?

Answer. HCFA has unified communications between computers by consolidating existing data communications networks. For remote communications, HCFA implemented a transition to the Value Added Network (VAN) via the National Library of Medicine contract. This provides uniform connectivity between the HCFA Data Center, Medicare contractor, Common Working File, State agency, Peer Review Organizations, and HCFA's regional offices. For local data communications traffic, HCFA has two HYPER channel links to the Social Security Administration's computer center and is evaluating local area networks for end user computer communication. HCFA is developing preliminary plans to migrate data communications to FTS 2000 networks.

COMPETITIVE BIDDING FOR MEDICAL EQUIPMENT

What plans does HCFA have to allow competitive bidding for medical equipment i.e., oxygen bottles which in the general market place can costs approximately $100 but their contracts allow more?

Answer. Congress has placed a moratorium on demonstration projects relating to alternative payment methods for Durable Medical Equipment through December 31, 1990. Accordingly, without legislative action HCFA can do nothing regarding competitive bidding prior to 1991.

Question. Is HCFA planning to help reduce medical costs by working bi-directional, i.e., at present they have provided programs for unilateral cuts for reimbursements? Do they have programs that will help provide cuts in the overhead of the care providers (hospitals, physicians)? For example, motivating factors that have driven up medical costs over the past 30 years have been such things like out of control malpractice rates and the lack of costs reforms that have allowed "irresponsible" lawsuits.

Answer. HCFA's mission is to administer the Medicare and Medicaid programs which primarily provide financing for health care services. As such, HCFA generally does not undertake reform initiatives outside its immediate purview of health care financing. In addition, the agency is careful to preserve the role of States in promoting such initiatives as tort reform.

However, HCFA has taken strong interest and provided significant input into the broader initiatives you mention. For instance, we are now actively involved in the Department's Effectiveness Initiative, which is under the leadership of the Public Health Service. This initiative will study the outcomes of patient care to determine which treatments are appropriate for which patients. This outcome information will be invaluable to physicians in providing quality care for their patients. Because this initiative will provide an objective basis for selecting the "right" treatment, physicians will be less subject to malpractice claims. Finally, this initiative will assure that purchasers receive full value for their health care dollar by assuring them that they are getting the best type of treatment known for their ailment.

MEDICARE DEMONSTRATION PROJECTS

Question. The demonstration project outlined in the Committee's report contemplates that Medicare Coordinators, as Medicare specialists, would be available to answer questions directly to beneficiaries in Social Security field offices. Do the current Medicare Coordinators provide Medicare information directly to beneficiaries or do they serve as resources for SSA employees on Medicare questions?

Answer. The Regional Medicare Coordinator serves primarily as the regional focal point to represent SSA Field Office concerns/issues with the

Health Care Financing Administration Regional Offices, other SSA components and the Medicare carrier. The Coordinator serves also as a resource person for district office staff in the Region. Of course, as occasions arise, the Coordinator may be asked to assist beneficiaries in understanding the Medicare program or to intervene in particularly difficult or "crisis" cases.

Question. Do the Medicare Coordinators perform any other functions described in the Committee report -- public outreach, training staff and volunteers at senior organizations or identifying and recommending changes to streamline the claims process?

Answer. In addition to the Regional Medicare Coordinator, each region has the option of designating a Field Office Coordinator whose main duties include the review of all Medicare related issuances to identify training needs and assure that appropriate Medicare training is conducted. They also may participate in public informational activities. Additionally, both the Regional and Field Office Coordinators handle key technical and operational contacts in and out of the office with representatives of organizations and agencies such as carriers and providers.

Question. Isn't it true that Medicare Coordinators are primarily placed in Social Security Regional Offices and are generally not accessible to beneficiaries seeking assistance at field offices? If not, how many Medicare Coordinators are currently working in Social Security field offices?

Answer. Medicare Coordinators are operational in all of the Social Security Administration's regions. Some regions have decided to have the coordinators in every field office, but all have placed them in those field offices with a high volume of Medicare issues and problems.

The Medicare Coordinators generally would not become involved in routine public inquiries. Social Security field offices employ service representatives who are available to handle routine Medicare inquiries.

Question. What progress has been made with respect to implementing PRO review of Health Maintenance Organizations and Competitive Medical Plans?

Answer. Medical review by Peer Review Organizations (PRO) of HMO/CMP inpatient and outpatient services was implemented throughout the nation for services rendered after April 1987. This review ensures that HMO/CMP services provided to Medicare beneficiaries are of adequate quality as required by the legislation. In order to determine if quality is being maintained in HMOs/CMPs, the PRO reviews a random sample of HMO/CMP cases from the following categories:

- 13 predetermined inpatient hospital conditions which may be indicative of problems with care preceding hospitalization,
- Regular inpatient hospital cases,
- Non-trauma deaths,
- Ambulatory care, and
- Hospital readmissions within 31 days.

The PROs also review beneficiary complaints about the quality of HMO/CMP services.

In addition, we have and are continuing to reevaluate the PRO Scope of Work (SOW) to refine the methodologies used. For example, until recently we had a requirement that the PROs review transfers from non-HMO hospitals to HMO hospitals because there was a perception that the HMOs might possibly force the transfer of unstable patients to hospitals that have a contract with the HMO. We analyzed the data about the results of this review and determined that the review category could be dropped because the results of this review indicated that only a few random problems were identified.

We will continue to analyze the effectiveness of the HMO/CMP review to determine where improvements can be made to make it more efficient and effective.

Question. What progress has been made in implementing the quality payment denial provisions as modified by OBRA 1989 (P.L. 101-239)?

Answer. Due to the complexity of implementing the provision and given the weight that such determinations will carry, we determined it best to implement the provision through the rulemaking process.

- The denial of payment for substandard care is a very sensitive issue particularly in light of the notice issued to the Medicare beneficiary regarding the denial of Medicare payment for such care.
- We published a Notice of Proposed Rulemaking in the *Federal Register* on January 18, 1989.
- A 60-day comment period resulted in 4,236 comments from individuals, professional organizations and medical associations which is evidence of the importance with which implementation of this provision is viewed by the public.

- o All of the comments have been thoroughly analyzed and evaluated and draft responses have been prepared and will appear as part of the final regulation.

- o We expect publication of the final rule by late spring, 1990 and actual implementation of the denial authority at least 60 days following publication of the final rule.

Question. For every dollar spent on the PRO program, how much is being saved?

Answer. We estimate that every $1.00 spent on the PRO program during the third round of contracts generates savings of $1.10. The savings result from net denials (denials upheld after reconsideration), changes due to DRG validation and changes to outliers (both day and cost). However, this estimate does not include savings from preadmission denials or savings from the "sentinel effect" (that is, either services not provided or DRGs not inflated because of the threat of PRO review) although these are very important aspects of the program.

Question. How does this compare with the cost savings for the first contract period? And for the second?

Answer. During the first contract period, the savings generated by the PRO program were approximately $1.20 for every $1.00 spent. During the second contract period, the savings were approximately $2.30 for every $1.00 spent. The increased savings during the second contract period over the first contract period were due to more focused review.

We expect the savings per dollar spent to decrease in the third contract period. This is because we measure savings primarily based on denials and DRG changes, and the increased emphasis on preprocedure/preadmission review (from 5 to 10 procedures) and beneficiary/provider outreach programs may reduce this figure. In other words, as the PRO program becomes more effective we expect fewer denials and DRG changes, but considerably more savings from the "sentinel effect" or cost avoidance (which are not included in the savings estimates).

ESTATE RECOVERIES

Recent reports by GAO (Medicaid: Recoveries From Nursing Home Residents' Estates Could Offset Program Costs, GAO/HRD-89-56) and the HHS Inspector General have identified significant budget saving potential through the establishment or expansion of estate recovery programs. GAO estimates that the six states it studied that lack such programs could recover about 585 million from recipients admitted to nursing homes in 1985.

Question. Do you agree with the GAO's estimates? What are the nationwide budget savings potential of recovery programs?

Answer. The GAO estimates are reasonable if one assumes that the six States in question would aggressively pursue the recoveries. It is our experience that all States do not implement programs with the same degree of zeal. HCFA has not developed an estimate of the amount of money which might be recoverable nationwide.

Question. GAO indicates that there is confusion about whether states can recover from the estates of recipients under the age of 65. What have you done or what do you plan to do to clarify HCFA guidance?

Answer. Both the Medicaid statute and regulations specifically indicate the situations when a State may recover from the estates of recipients under the age of 65. We disagree with OIG that States are confused about the recovery policy. Most States have recovery provisions which require that recoveries be made from the estates of recipients under age 65 regardless whether joint tenancy right of survivorship clauses exist.

The State may recover funds for Medicaid claims paid on behalf of an individual from the estate when the individual is institutionalized and only (1) after the death of the individual's surviving spouse; (2) when the individual has4 no surviving children under the age of 21 or blind or disabled; and (3) in the case of liens, when there is no sibling of the individual residing in the house (who resided there for at least one year immediately before the date of the individuals's admission and continues to reside there) or son or daughter of the individual (who resided there for at least two years immediately before the date of the individual's admission and continues to reside there). We disagree with OIG that confusion exists about the recovery policy, and note that most States have such policies already in place.

STATE RECOVERY PROGRAMS

Question. What has HCFA done to encourage states to establish or expand recovery programs? Has HCFA done anything to evaluate and publish best practices in response to the GAO and IG reports?

Answer. HCFA has developed and carried out an aggressive marketing campaign in the TPL arena. As part of that marketing effort, HCFA has marketed estate recoveries. Presentations have been made to numerous groups including the State Medicaid Directors, National Conference of State Legislatures, and the National Association of State Budget Officers. In addition, HCFA has published a Best Practices Guide which includes estate recovery programs which work.

QUESTIONS SUBMITTED BY SENATOR PETE DOMENICI

CONTINGENCY FUND(S)

In the "Program Management" appropriations request, it appears that there are two separate contingency funds, one for unanticipated workloads and one for unanticipated costs associated with last year's reconciliation bill. Over the past few years, a single contingency fund of $100 million was requested. Now, a second contingency of $73 million is requested. Contingency funds pose special "scorekeeping" problems.

Question. Please explain the logic for two separate contingency fund requests.

Answer. Contingency funds have historically been provided to fund either activities that are not anticipated at the time of budget development or for unanticipated workload increases. We have separated our contingency request this year in an attempt to make more specific what events will justify a release of funds. One fund is for activities related to OBRA 89 implementation and the expenses related to contractor terminations and consolidations, and the other fund is for unanticipated growth of operational activities (claims processing, hearings, correspondence, etc.)

Question. Please explain how you assume outlays for part of one contingency for costs not "fully anticipated", but you do not assume outlays for the rest of the contingency for "costs and workloads not fully anticipated" (page 5 of your justification). Please be specific about why you assume outlays for exactly one-half of one of the contingencies, as opposed to all, none, or some other fraction, and what the distinction is between the funds that you score as having outlays and the funds that you do not.

Answer. As part of the budget negotiations between HCFA, HHS and OMB, it was agreed that half of the $73 million contingency for OBRA implementation would be needed. It may be necessary to request the outlay of additional funds in FY 1991, however, this at least gives us specific OBRA 89 implementation funds at the beginning of the year.

Question. What is your current estimate of the costs in administering the provisions of P.L. 101-239 (the 1989 reconciliation bill)? In what line items of your Budget are these costs reflected?

Answer. We believe OBRA 89 implementation will cost between $70 and $90 million dollars. The current budget contains $4.5 million for productivity investments related to OBRA 89, about $20 million for claims processing and professional relation activities and $36.5 million in the outlayed contingency for unspecified activities.

RELEASE OF THE CONTINGENCY FUND

Last year, I asked several questions about the legal requirements for offsetting the release of the contingency funds under the current Gramm-Rudman-Hollings restrictions.

Question. Were any of the contingency funds Congress made available last year released?

Answer. Yes, $7.5 million was released for a special Medicare Secondary Payer data match.

Question. If so, were the released funds spent?

Answer. Not all the funds were spent because not all the contractors provided the data match material necessary to perform the comparison of private insurance enrollees and Medicare beneficiaries.

Question. Was an offset proposed? Did you effectuate the offset?

Answer. The release of the funds was not contingent on an offset.

PROPER BUDGETARY TREATMENT OF PEER REVIEW ORGANIZATIONS

Last year, I asked Dr. Roper about whether Peer Review Organizations (PROs) should be subject to appropriations. Presently, HHS and OMB determine the funding level for PROs without Congressional approval, and the program has now grown so outlays are about $700 million every 2 years. Dr. Roper responded, and I will quote:

> "We believe that funding for PROs should be through the annual appropriations process, rather than through direct apportionment from the Medicare Trust Funds (as is currently done). The Office of Management and Budget also supports this position.
>
> The size and cost of the PRO program have grown considerably since the original legislation was enacted six years ago. In view of the substantial cost of the program, it would be appropriate for elected officials to determine PRO activity and related funding levels, rather than to allow Executive agencies to continue to make such decisions.

The Appropriations process would bring PRO funding under the Congressional oversight process, would eliminate ambiguities concerning Gramm-Rudman-Hollings offsets, and would permit HCFA to seek additional funding to implement legislative changes to the program, when necessary, from Congress, rather than a reapportionment request."

I was pleased with this response, as it indicated the Administration was willing to forego its nearly absolute control of funding over this program, to share it with Congress, as is the case with nearly every other similar activity. However, when the President's Budget arrived, it did not seek to fund PROs through the Appropriations process.

Question. Has the Administration's position changed with regard to how the funding level for PROs should be determined? Do you still support appropriating funds for PROs?

Answer. The Administration's position has not changed. We continue to believe that a program of this size and importance should be included in the Congressional Appropriations process.

PEER REVIEW ORGANIZATIONS

Question. How much do you plan to spend on PROs in FYs 1990 and 1991, and how much will be obligated in each of those years? How much was previously obligated?

Answer. We estimate that PRO outlays in FY 1990 will be $295.5 million and in FY 1991 will be approximately $323.5 million. In FY 1990 we-expect to obligate $332.6 million and we estimate FY 1991 obligations of $348.5 million. Through the end of FY 1989 HCFA has obligated $552.5 million for the current (i.e., third) PRO contract cycle, plus another $3 million for PRO review of CHAMPUS cases. The Department of Defense has reimbursed us for the cost of the CHAMPUS reviews.

CLAIMS PAYMENT VOLUME

Question. On page 75 of your Appropriations justifications, you project essentially no claims volume increases for Medicare in FY 1991. Medicare claims volume has grown much faster than that recently. Could you detail better the basis for your 1990 and 1991 projections, separating actual 1989 and projected claims into those required for catastrophic health insurance and for the rest of Medicare?

Answer. The repeal of catastrophic primarily affects FY 1991 as that was when the Part B impact of catastrophic would become significant. We are projecting historical growth patterns to carry into 1990, however we believe there are signs of a decline in the historical growth rates. We have budgeted accordingly in FY 1991. As in previous years, the budget contains a contingency fund reserved for unanticipated workload growth.

Question. Please explain the differences in estimated 1990 claims volume, relative to last year's justification.

Answer. The only difference is we downsized our Part A workload estimate by about 10 million claims due to the repeal of catastrophic.

CHANGE IN CLAIMS PROCESSING CYCLE

Question. Relative to paying claims at an average constant speed over the FY 1989-1991 period, please identify the number of added claims that your justification assumes will be paid in FY 1990 (and the number of fewer claims it assumes will be paid in FY 1991) as a result of the notice HCFA issued that indicated claims would be paid as quickly as possible in 1990, and then returned to previous standards in 1991.

Answer. We believe about 7 - 10 million claims which would have been processed in FY 1991 will be processed in FY 1990.

Question. Will or did the intermediaries start to pay claims faster immediately in FY 1990, or will they wait and pay added claims at the end of FY 1990? Similarly, when will the slowdown in claims payment (relative to the FY 1990 speed) occur in 1991 -- immediately at the beginning of October 1990, or gradually over the course of the year? If the changes are sudden, how will the fiscal intermediaries absorb the extra work in the "crunch weeks" of FY 1990, and what will they do during the "down weeks" in FY 1991.

Answer. The floor will be removed for the last quarter of FY 1990 and reimposed immediately with the beginning of FY 1991. The removal of the floor means that claims will not have to be suspended after processing and held for a period of time prior to payment. The existence of the floor does not affect the timeliness of claims processing. With or without the floor, claims are processed immediately upon receipt. The implementation

of the floor resulted in contractors holding processed claims in a pending file prior to payment. The elimination of the floor merely eliminates the need for the pending file. However, some additional work will have to be accomplished, and we expect it can be accomplished with existing resources.

Question. What is your estimate of the interest that will be lost by the Medicare Trust Funds (or overall government) as a result of paying bills faster in FY 1990 (and part of FY 1991 if the slowdown in FY 1991 is gradual)?

Answer. We expect the interest loss to be about $20 million dollars.

Question. What is the budgetary effect of the added claims payments volume in FY 1990 and FY 1991? Will the FY 1992 current services estimates adjust for the temporarily reduced number of Medicare claims paid in 1991?

Answer. We expect the administrative cost of the removal and reinstatement of the floor to be minimal. In addition, we expect no significant impact on FY 1992. Regarding benefit payments, we expect about $1.4 billion dollars in benefit payments to be made in FY 1990 that would have been made in FY 1991.

The changes in claims volume in FYs 1990 and 1991 do not affect the cash benefits baseline in FY 1992 and later. The benefits baselines are first projected based on incurred costs from the date of service. A separate adjustment is then made to reflect lags in claims payment. Thus the date a claim is actually paid does not affect the incurred baseline projection. Further, the removal and reinstatement of the floor did not modify the factor used for lags in claims payment after FY 1991.

WORKLOAD FOR CATASTROPHIC HEALTH INSURANCE

Question. The Medicare administration appropriation last year assumed the enactment of catastrophic health insurance. It was subsequently repealed. Could you please identify how the FY 1990 funds that you requested in the FY 1990 justification for catastrophic health insurance are now being allocated? Please separately identify funds that:

- were never appropriated;
- funds that were sequestered;
- funds that are being used to pay claims faster in FY 1990;
- funds being used for productivity investments; and
- funds being used for other purposes (please identify).

Answer. The FY 1990 HCFA program management appropriation contained $293 million for catastrophic activities. We have allocated the money in the following manner:

Congressional Action (MClure and Byrd amendments)	$47M
Catastrophic phase down-HCFA	60M
Catastrophic phase down-SSA	45M
Restoration of payment safeguards	114M
Federal pay raise	7M
Sequester	20M
Total	$293M

MEDICARE HEARINGS AND RECONSIDERATIONS

Question. You have estimated that the number of hearings and reconsiderations for disputed Medicare claims will increase by 13 percent to 6.1 million, yet you propose to reduce funding by over 10 percent. Please describe how added hearings can be financed with less funding in 1991?

Answer. During FY 1989, HCFA implemented new procedures aimed at streamlining the appeals process to reduce administrative costs and processing time.

In particular, the following major changes were effected for carrier appeals operations, which account for over 87 percent of the hearings/reconsiderations workload:

- The use of simplified, shorter decision letters;
- Expanded use of on-the-record decisions; and
- Restricted use of reopenings, formal and informal.

We anticipate that the efficiencies achieved through implementation of these changes to the hearings and reconsiderations procedures will result in lower unit cost and a higher level of consistency among contractors. This should enhance national uniformity, and permit contractors to render decisions of higher quality within statutory timeframes. Additionally, the overall effect of this HCFA initiative on the Medicare Contractor Budget will be the ability to process more hearings and reconsiderations at a reduced average unit cost. Accordingly, we believe we can process more hearings with less funding.

Question. Please provide a breakdown of hearings and reconsiderations by type of workload (e.g., telephone interview, face-to-face, or other methods).

Answer. A schedule depicting hearing and reconsideration workload information is provided. This schedule is for the first quarter of FY 1990 and is current as of February 13, 1990.

OCTOBER-DECEMBER 1989 APPEALS PROCESSED

	Phone	On The Record	In-Person	Withdrawn	Total
Carriers					
Reviews		1,451,214		126,617	1,577,831
Hearings	1,339	9,716	1,435	4,914	17,404
ALJ Hearings			72	81	153
Intermediaries					
Reconsiderations		4,805		1,419	6,224
Reviews		16,772		2,755	19,527
Hearings	85	482	172	116	855
ALJ Hearings			2,150	251	2,401

CARRIER PREPAYMENT REVIEW

Question. You propose to extend the authority of Part B carriers to require prior authorization for certain medical equipment and estimate $64 million in savings. Please explain how these savings would materialize.

Answer. In developing an estimate of savings for the proposal to extend the authority to carriers to prior authorize medical services and equipment, we made a number of assumptions:

- This authority would be applied selectively to expensive services and equipment.

> Application of this authority would be restricted to instances of demonstrated evidence of over utilization of Part B services by the supplier or the administering or ordering physician.

We believe that savings will materialize in two distinct ways. First, physicians will order and perform fewer unnecessary expensive services and tests, based on the knowledge that Medicare will not pay for them without prior authorization.

Second, savings will be achieved through carrier denials of requests for prior authorization.

Question. Is legislation required for this prior authorization activity?

Answer. Yes. We do not believe that current law provides authority for carriers to prior authorize medical services and equipment.

Question. If Congress granted this authority, what would be the added administrative cost associated with this activity? How would you finance this activity?

Answer. The added administrative cost to carriers would result primarily from the need to hire additional staff to process prior authorization requests, as well as some minimal costs for claims processing systems changes. It would be financed by using the regular contingency fund set aside in the FY 1991 budget.

RATE OF RETURN ON MEDICARE PAYMENT SAFEGUARDS

Question. Your budget indicates that an investment of about $330 million in payment safeguard activities yield program savings in Medicare of about $3.8 billion. That's an average return of about 11:1. To determine appropriate funding levels, we must know more about the marginal return on this investment. Does the Budget request assumes that the marginal return for each of these activities is 1 for 1 or less?

Answer. No. We have not performed any studies to determine the marginal return of the payment safeguard elements. However, we believe the point of diminishing returns has not been reached. Although we don't think it is necessary, we believe that an additional $50 to $100 million could be incrementally added to payment safeguard investments without diminishing the return ratio.

Question. If not, why weren't added funds for added payment safeguard activities requested to reduce the deficit?

Answer. Although we have not significantly increased total payment safeguard funding, we have reallocated funds to the areas of payment safeguards which have the greatest return. We believe our payment safeguard funding level strikes a good balance between our responsibilities to process claims and protect program payments. The Congressional Budget Office does not score payment safeguard savings against the deficit. Accordingly, payment safeguard funding would not impact deficit projections.

Question. The average return in categories of payment safeguards varies greatly. For example, Medicare Secondary Payor (MSP) activities in Part A return nearly 50:1, compared to considerably lesser average returns for other activities. Even assuming the payment safeguard budget were fixed, couldn't you increase MSP activities (and reduce other payment safeguard activities) and save added Medicare outlays?

Answer. In FY 1990 and 1991 we have put relatively more emphasis on Part A MSP than in prior years. However, all payment safeguard activities are important and any major reductions in Medical Review or Provider Audit would not only take away direct savings, but also reduce the deterrent effect and open the doors to abusive billing practices.

Question. How is the HCFA/SSA/IRS data match for MSP (required in the 1989 reconciliation bill) progressing? Will Congress see the $300 million in FY 1990 savings that we assumed from this provision? What is your best current estimate of added MSP savings from this initiative in FY 1991 and later years?

Answer. The Health Care Financing Administration (HCFA)/Social Security Administration (SSA)/Internal Revenue Service (IRS) data match is progressing satisfactorily. There are several administrative actions that must occur before the exchange can take place. For example, the data exchange is subject to the provisions of the Computer Matching and Privacy Protection Act. HCFA is taking the lead on developing the appropriate clearances and Federal Register Notice. However, these materials must be cleared by two Departmental Data Integrity Boards.

IRS has indicated that they will provide the initial match of spouses from 1987 and 1988 returns to SSA by June 1990. The statute provides SSA with an additional 120 days to identify those beneficiaries and/or spouses of beneficiaries with earnings.

In an effort to expedite the project, HCFA is requesting SSA to provide data on Medicare beneficiaries who are workers. In this way, we hope to begin development with employers by July 1990 on a phased basis, rather than awaiting for the completed IRS data exchange of beneficiaries and spouses. If we are successful in this effort, we expect to provide intermediaries and carriers with initial information on which to initiate recoveries of mistaken payments and identification of Medicare secondary payment (MSP) situations to avoid further mistaken payments beginning in September 1990.

We do not anticipate obtaining significant savings for fiscal year (FY) 1990. Although we expect some savings will accrue due to increased voluntary compliance with the MSP provisions arising from an awareness on the part of third party payers of the project, recoveries will not begin in FY 1990. However, we do anticipate significant savings for FY 1991. Our current estimates project $400 million in FY 1991 savings and $200 million in FY 1992 savings, before this provision sunsets. These savings estimates are related exclusively to recovery of mistaken Medicare primary payment. Further savings, although not specifically identifiable, will arise from avoidance of Medicare primary payments on current claims as a result of identifications made through the data match project.

STUDY ON PAYMENT SAFEGUARDS

Question. I believe we should have the best information possible on the marginal return and added funds going into payment safeguards activities. Will HHS and HCFA consider having a neutral outside consultant do a major study of the payment safeguard activity, so we could get a firmer idea about where the marginal return of these dollars is 1 for 1?

Answer. Yes, HCFA will consider having a neutral outside consultant do a major study of the payment safeguard activity.

HOSPITAL INSURANCE SOLVENCY

Question. The last long-range actuarial report (1988) we received for the Hospital Insurance Trust Fund indicated it would become insolvent by the year 2005 under the "II-B" assumptions. What effect would the adoption of the President's Budget proposals have on the solvency of the Medicare Hospital Insurance Trust Fund?

Answer. The President's Budget proposals would raise the Hospital Insurance (HI) Trust Fund's FY 1995 end-of-year balance from $205 billion to $244 billion. One should note that this $39 billion improvement in the trust fund's status results from both income and outlay proposals. Including all State and local government employees under Medicare ensures that these employees contribute their fair share to the HI Trust Fund. The President's Budget outlay proposals, by appropriately restraining growth in hospital and related Part A services, further improve the HI Trust Fund's projected balance.

The HI Trustees did not project the long-range status of the HI Trust Fund last year, primarily due to complications and delays in estimating the new Catastrophic income streams. Thus, the 1988 report you referred to contains the latest estimate of the trust fund's long-range solvency. A revised report on the status of the HI Trust Fund will be available in the upcoming 1990 Trustees' Report.

RURAL HEALTH TRANSITION GRANTS

Question. You requested no funds for the rural health transition grant program. Your justification gave no indication as to why. Why do you propose no funding for the rural health transition grant program in FY 1991?

Answer. The original set of grants awarded in FY 1989 under the Rural Health Care Transition Grant program were made for a 2-year period as authorized by section 4005(e) of OBRA 87. The first year funding for these grants was made from the FY 1989 appropriation for this program and the second year continuation funding for these grants will be made from the FY 1990 appropriation for this program. The FY 1990 appropriation also permits the award of additional new 3-year grants as authorized by section 6003(g)(4) of OBRA 89 which amended section 4005(e) of OBRA 87. We intend to evaluate the impact of these grants and determine their effectiveness in preserving access prior to making funding decisions beyond FY 1990.

Question. Have any funds been included for rural transition grants in FY 1992 and beyond in the President's budget, or does the President propose to terminate the grants?

Answer. No decision will be made about future funding requests for this program until we complete our evaluation of its effectiveness.

Question. How many applications have you received for rural health transition grants? How many were denied? Were all those denied unworthy, or aren't there enough funds to pay for all the good requests?

Answer. As a result of our FY 1989 rural health care transition grant solicitation, we received 704 applications. With an appropriation of $8,892,000 and a limitation of $50,000 per grant we were able to fund 184 of the most worthy applications with 520 applications being disapproved. The 184 applications which were approved were both technically acceptable and geographically representative.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

LASAGNA COMMITTEE

The National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS (the Lasagna Committee) has recommended that Medicare carriers' discretion be restricted in connection with coverage decisions about drugs.

Question. Does HCFA intend to follow this recommendation, and if not, why not?

Answer. Current Medicare policy provides for coverage of drugs (that is, drugs and biologicals) for indications approved by the FDA in the labeling. Carriers are therefore required to pay for labeled indications. They may decide, in addition, to cover a drug for an unlabeled indication based on medical practice in their respective locales, so long as such use is not specifically precluded by the FDA or HCFA. In connection with implementation of the Medicare Catastrophic Coverage Act of 1988 (MCCA), HCFA planned to mandate the use of the three major drug compendia for coverage of drugs as authorized by that Act. In that context, we were also studying the issue of national uniformity of drug coverage that remained outside of the coverage provisions of the MCCA. Since repeal of the MCCA, there is no specific statutory provision to use as a basis for mandatory uniform national drug coverage, but we continue to consider ways to achieve it.

Question. The Lasagna Committee also recommended that Medicare automatically cover any unlabeled drug indication recognized in one of the three major medical compendia. Does HCFA intend to follow this recommendation, and if not, why not?

Answer. As indicated in the answer to question 1, under the MCCA, we had clear authority to mandate the use of drug compendia for use in making coverage decisions about drugs covered by the MCCA. (In addition, in committee language, Congress indicated its intent that we consider use of the U.S. Pharmacopoeia, the AMA Drug Evaluations, and the American Hospital Formulary Service.) In view of the repeal of MCCA, we are considering whether and to what extent, national uniformity can be promoted.

COVERAGE OF UNLABELED INDICATIONS FOR DRUGS

Question. Does HCFA have any data indicating the cost of the individualized carrier decisions with respect to coverage of unlabeled indications for drugs?

Answer. No.

Question. How does that cost compare with the savings realized from denial of coverage for these indications?

Answer. Data not available.

Question. Is there not a potential conflict of interest when such decisions are left to individual carrier discretion while at the same time these carriers, in their private business, have been increasingly restrictive in their own coverage decisions?

Answer. Carriers are left with considerable discretion on which indications to cover. The Medicare program has been designed from its inception in this manner. Individual Medicare coverage decisions are independent from a carrier's private business but are to be based on the current medical policy of the community. Often, this is reflected in what they are doing in their private business.

Question. I am very concerned about claims processing and want to be sure your budget request is adequate for the prompt processing of beneficiary claims. Your budget justification projects a decrease in the Part A claims workload from FY 90 to FY 91 and a very slight increase in Part B claims workload. In recent years, the annual increases in both Part A and Part B workload have been much greater than these modest projections. In fact, from FY 89 to FY 90, the Part A claims workload grew by 10.3% and the Part B claims workload by 13.6%. Please provide a detailed explanation of the projected workloads for FY 91.

Answer. In late FY 1989 a trend of declining growth in benefit payments emerged. In addition, claim receipts were lower over the last three months of FY 1989 than expected. These factors coupled with the repeal of catastrophic and the speed up of claims processing in FY 1990 lead us to believe that claims processed in FY 1991 may be much less than historic trends would indicate. As in previous years, we have requested that $100 million of the contractor contingency be reserved for unanticipated workload growth.

SOCIAL SECURITY ADMINISTRATION

STATEMENT OF GWENDOLYN S. KING, COMMISSIONER

OPENING REMARKS

Senator HARKIN. We will now hear testimony from the Social Security Administration. And we welcome Gwendolyn King, the new Commissioner in her first appearance before the subcommittee.

For the first time in 5 years your agency is not requesting a staffing cut. Well, that is definitely a step in the right direction. But the bad news is the rate of telephone busy signals. Another piece of bad news is too many cases of wrongly removing SSI recipients from the roles and a persistent backlog in handling disability appeals—an area that you know I am very interested in.

It is not surprising that the survey your agency conducted last year revealed that most employees feel overwhelmed, that you face widespread morale problems. I can sure understand that. Projections of the elderly population indicate that the Social Security Administration's workload will continue to grow in the years ahead.

So, Commissioner King, welcome again to the subcommittee. Your statement will be made a part of the record in its entirety. I am going to ask you to highlight it, or to make those comments or statements that you think that we should pay the most attention to.

SUMMARY OF REQUEST

Ms. KING. Thank you very much, Mr. Chairman. I do have a brief statement I would like to read.

I am pleased to be here today to present the fiscal year 1991 appropriation requests of the Social Security Administration. These requests total $20.2 billion in budget authority. Those moneys will be utilized to administer the old-age, survivors and disability insurance programs, fund administrative costs and benefits under the Supplemental Security Income Program, provide special benefits for disabled coal miners and perform certain administrative functions for the Medicare Program.

In the full statement I have submitted for the record, I am providing the committee with the full breakdown of the appropriation requests. In the brief time I have I want to talk about the impact those funds will have on the Social Security Program and the millions of Americans who depend on it.

Social Security is unique among Federal programs because of the trust the public has invested in it, and because of the direct and vitally important effect it has on the lives and well-being of so many people. The Social Security Administration provides not only retirement support for Americans in their retirement years, but an entire package of social insurance protection. It provides protection against the financial hardship which can accompany a disability or the premature death of a household breadwinner; and economically disadvantaged elderly, disabled and blind people look to SSA for basic minimum financial assistance.

We have the responsibility to provide every one of our beneficiaries the kind of compassionate, courteous, considerate, efficient and accurate service he or she deserves. We have the responsibility to protect the American people's investment in the Social Security trust funds, and to instill public confidence in SSA's programs.

We also have the responsibility to create an environment that assures an SSA work force that is highly skilled, motivated and dedicated to meeting the public's needs. Fulfilling those responsibilities, Mr. Chairman, is my goal as Commissioner of this Agency.

This appropriation request reflects the minimum resources necessary to achieve that goal. The budget request I am submitting will stabilize SSA's employment at about 63,000 full-time equivalents. This figure represents the culmination of 6 years of dramatic downsizing during which FTE levels dropped by more than 17,000.

These employment reductions have saved the Government almost $2 billion and continue to save about $600 million annually. At the same time, though, public demand for service has increased, and new technology has been implemented to help meet those demands.

Mr. Chairman, Social Security numbers are now issued in about 10 days, down from 6 weeks just a few years ago. Annual earnings items are posted to workers' records in about 5 rather than 15 months. And, by processing 95 percent of all benefit claims through the modernized claims system, payments are made more efficiently and in a more timely way.

This budget requests that SSA's employment be stabilized at 63,000 full-time equivalents. It also reflects continuing productivity improvement and initiatives to control spending and find more efficient ways to operate. This budget also reflects the fact that I will be asking SSA's employees to reach farther and break new ground in the service we provide. One major priority will be SSI outreach.

SSA's fiscal year 1991 systems budget focuses on critical needs, including improving the flexibility of the agency's programmatic software, automated data processing equipment and services for the State agencies which make disability determinations, and also basic support areas that have in recent years faced severe cutbacks.

And, Mr. Chairman, this budget enhances the nationwide toll-free telephone service SSA implemented in October of last year. While maintaining face-to-face service through our 1,300 field offices that people have trusted for so many years, the 800 number provides another option for people who like to make appointments to file claims, or handle other routine business.

SOCIAL SECURITY TRUST FUNDS

In closing, Mr. Chairman, I would like to say a few words about the Social Security trust funds. Administrative expenses remain a small fraction of the overall trust fund operations. For fiscal year 1991, administrative expenses are estimated to be about eighttenths of 1 percent of anticipated contribution income to the OASI and DI trust funds under current law and 1 percent of benefit payments.

The budget shows steadily increasing balances in the OASI and DI trust funds. To meet our obligation to tomorrow's elderly, and disabled and surviving families, the reserve level will be at $299 billion by the end of fiscal year 1991. On Monday, I testified before the Senate Finance Committee on the subject of trust funds and their relationship to the deficit.

I want to repeat something I said at that hearing. As Commissioner of Social Security, I have a unique responsibility to ensure that any discussion of Social Security and its reserves enhance and not erode public understanding of and confidence in the Social Security system. This appropriation request is intended to maintain a program that deserves the public's confidence.

It also reflects my commitment to the employees of the Social Security Administration whom I have asked to enter into a partnership with me to ensure the efficient operation of this program. Social Security has paid benefits each month on time for the last 50 years. It will continue to do so.

I also want to work in partnership with you and your colleagues, Mr. Chairman, to deliver quality public service and to safeguard the Social Security Programs for our current and future beneficiaries.

I would be pleased now to answer any questions you have.

Senator HARKIN. Thank you very much for your statement and for completing a good first year on the job.

Ms. KING. Thank you, sir.

SSI OUTREACH

Senator HARKIN. I want to talk a little bit about the SSI outreach program. The 1990 appropriation included $3.5 million for this new program. What have you done to implement this program?

Ms. KING. Mr. Chairman, SSI outreach, as you probably have heard, is one of my priorities. We have just published in the Federal Register a notice requesting ideas on the content of priority areas for grants and cooperative agreements to facilitate outreach to our most vulnerable citizens. In the interim we have been holding a number of forums with community organizations that are in a good position to be partners with us as we attempt to identify people in their local communities who are eligible for this very important program.

One of the things that we are very keen on is ensuring cooperation with our sister agencies within the Department of Health and Human Services. To that end, we have effected a memorandum of understanding with the Administration on Aging, which I know was an agency you were interested in seeing participate in this effort, as well as with the Health Care Financing Administration.

We have stated clearly what our individual and collective efforts should be, so that we are not duplicating effort. We want there to be a clear understanding of our outreach plans not only at central office in Baltimore, but out in each one of the communities we are expected to serve around the Nation. We are working in cooperation with community groups already in place and eager to work with us.

What we are trying to put in place is a system that will be there long after the dollars for this outreach effort are gone. We hope that we will seed those communities so that they will blossom forth a number of activities geared toward identifying low-income elderly, blind, disabled adults and children, and homeless people—all those who may be eligible for this very important program. As long as one eligible person goes without help, then we have a lot of work to do.

Senator HARKIN. You will do all on this on $3.5 million?

Ms. KING. I believe that the important thing we are finding out—and I have been out there in the community, Mr. Chairman, and I have talked to people from Boston to Seattle—the important thing for us is not primarily the money. It is tapping into those points of light that exist in every community, that are reaching out to people in need, and making sure they know that we—Social Security—stand ready to take that application, ready to assist that person to get into the mainstream.

What we are doing with our dollars is simply removing barriers at this point, and encouraging as many people to participate in this program as possible. It is working. We will see at the end of this year a number of proposals from community organizations that we have invited to come in and try to help us. Then, by the end of next fiscal year, I think we will have a good bit of information about what else we need to do to ensure that we have tapped into all those resources in communities that have existed for a long time, but may not have known about SSI, and may not have known that, indeed, Social Security Administration employees do leave their offices to go to where people are, to take that claim, and to help people enroll in the program.

Senator HARKIN. By when did you say?

Ms. KING. We are going to be letting contracts this year, and we will have a good deal of information about how we are doing in SSI outreach by this time next year.

Some of those projects that we will pay for may indeed need to go for more than a year's period of time. So that information may be coming in a little more slowly. But we are already gathering not only information, but a good deal of interest. We are tapping into the biggest resource that we could tap into, and that is those community organizations, our area agencies on aging, all those groups that are currently in place in communities. We are letting them know about us.

The other thing we have on the drawing board, that we will be launching very shortly, is an extensive public affairs campaign which is going out through our 1,300 field offices to let people know about SSI outreach. I, 2 weeks ago, launched an SSI outreach project in cooperation with AARP in Essex County, NJ, which I believe is really going to reach into that community and find people who are eligible for our program and bring them into the program. We are doing that all over the country, as you know.

RESOURCES FOR OUTREACH

Senator HARKIN. So, the $3.5 million that you got in fiscal year 1990 is sufficient to cover for fiscal year 1991 also?

Ms. KING. What I am saying is that we have yet to——

Senator HARKIN. It is not in your budget request. That is what I am saying.

Ms. KING. We have yet to expend the $3 million provided to us this year. And with the resources AOA and HCFA are also putting into this effort, the Department of Health and Human Services is spending well over $3.5 million for outreach.

The bottom line though is that while we are getting ready to go flat out with this program, by the time we review those proposals that come in to us as a result of the notice we have published in the Federal Register and make awards, most of those activities will not be getting up and running until toward the end of this year. Then we will be working throughout the year with those grantees, to ensure that the outreach efforts are ongoing.

You will be hearing more from us later, Mr. Chairman, probably this time next year. Currently, we are on a good track. I think one of the things we have not done is that we have not flashed the bucks and encouraged people to come to us who have no interest in participating in this program.

We really do have people who are committed to working within their communities to identify people for this important program, and we want to work with them.

Senator HARKIN. Well, I hope you are right. But I feel like you have just sort of pushed your finger into a balloon. All those funds for those other agencies come through this subcommittee too.

Ms. KING. Yes.

Senator HARKIN. They are strapped for personnel. You are telling me your workload is going up. And you are down to the bare bones in the number of people you have got, the same thing is true in a lot of those other human service agencies. Now, they say they want to do outreach for SSI, you want to shift the burden to them, and let those points of light go out there and do all the outreach, and they are going to come back to us and say we need more money.

Ms. KING. What we have done, I think, by our memorandum of understanding is quite to the contrary. What we have done is to identify for each agency exactly what it is we are doing, to cut down on duplication, to ensure that we are working in sync with each other. We are working cooperatively to get our message out in those communities, and I think you are going to see a better result.

Senator HARKIN. I sure hope so. But I happen to know what it is like to go out for SSI outreach. That is not simply a matter of getting on the radio, or putting a nice poster some place and saying, if you are eligible for SSI call. These people do not know if they are eligible for SSI.

You've got to sit down with people. A lot of times it takes a case worker to actually go out to someone's house. A lot of times, these are people that do not come into community centers. They do not go to congregate meal programs. You have got to go out and actually get them. And a case worker has to sit down and find out if they are really eligible? What is their income, what is their status, what is their disability? Are they really eligible? That takes time.

Ms. KING. Yes; it does. One of the links that we are accomplishing is working with other community organizations that are doing that kind of outreach. We now are making the connection and letting them know who we are. We are going out to pick up those people they identify, bring them in, ensure that they get that medical examination if needed to qualify for disability benefits.

OUTREACH THROUGH COMMUNITY ORGANIZATIONS

Senator HARKIN. You are saying that a lot of these agencies have that information already. You are just not tapping into it to get that information?

Ms. KING. What I am saying is a lot of those external organizations are identifying people in need, but did not know where to go from there. Now they are learning about SSI, and they know we are there. They know to call us. We are going to ensure that that information is carried out into local communities.

Senator HARKIN. But, now, Ms. King, now just a second. Maybe I misinterpreted what you just said. It sounded like what you just said to me is that a lot of these agencies out there have this information, but they did not know that they could go to SSI?

Ms. KING. One of the things we are finding out is that not everybody is aware of the SSI program.

Senator HARKIN. But those agencies out there, and the people that run them, they are aware of it.

Ms. KING. You mean the Federal agencies. Of course, they are aware of the program.

Senator HARKIN. Agencies on aging.

Ms. KING. Yes.

Senator HARKIN. There are community action agencies that are out there.

Ms. KING. That is right. We are also now, Mr. Chairman, working with organizations that were previously not working cooperatively, or at all with the Federal Government. We are working not only with State agencies, but local agencies. We are working with a lot of nonprofit organizations.

Senator HARKIN. But I still would think, a lot of the time, that the people that run those agencies, they are not dummies. They know how to tap into existing programs. And I guess I just find it hard to believe that these agencies have all these people in there that are eligible for SSI, but they did not know they could go to Social Security to get help. The individual out there living by herself/himself, the disabled person that is eligible, it is these people that do not understand that they are eligible.

Ms. KING. Believe me, Mr. Chairman, I did not make this up. When we held all those meetings with the nonprofit organizations and with all the others who came in at our invitation to begin to formulate some way of moving forward together for SSI outreach, this is what they told us.

The SSI program, indeed, has been on the books since 1974. But the program that is operating today has become broader and a lot more complicated, and people may not know that they are eligible.

That is why it is important for us to explain our role and our program to people who are in a good position to work as partners with us.

800 NUMBER TELEPHONE SERVICE

Senator HARKIN. I want to refer to the chart on the busy signal. It is obvious there are a lot of people who are trying to call, who are getting a busy signal, instead of an answer to a question. To me this is serious, as you are converting the entire country to the 800 system. We need to know whether or not it is going to work out. I am sure you have reviewed the plans for and monitored the implementation of this system.

What seems to be the problem that we are having with the number of busy signals?

Ms. KING. Mr. Chairman, in fact what you see is a program that is working too well. In planning for this program, apparently, SSA missed the mark and planned for the 800 number to handle about 250,000 calls a day. Indeed, during peak times, our experience has been that we can get anywhere from 800,000 to 1.5 million calls a day.

We have identified what the peak times are. We already knew that peak months would be January and February. What we did not realize is that when we went nationwide with 800 number service, we would be able to capture all the calls previously going into the 1,300 field offices.

We had no way of knowing how many people calling those field offices before were actually getting busy signals. The new technology that we have with the 800 number captures all those calls coming in, including information on busy signal rates not previously available. What we learned initially in October and November was that we had to go back to our old economics 101, government 101 books to figure out a way to better dispatch hour-by-hour our employees handling the 800 telephone lines.

We made some adjustments. I have removed and reinstalled some 1,000 telephone lines going back into 362 field offices, which had been pulled once the 800 number went in. We have reinstalled local lines to alleviate demand on the 800 number wherever we could.

Senator HARKIN. So that 800 number rings where?

Ms. KING. The 800 number will ring when people call the 800 number. But the minute they ask for a local telephone number, our teleservice representatives have been instructed to give that number, if the people want to work with their local offices.

I found it incredible that our telephone representatives were being told that they could not give out the field office telephone number, if somebody really wanted to work with someone they had been working with in the local office for the last 10 years. We have tried to correct that situation.

In Social Security, Mr. Chairman, we have a new concept of job-sharing. In most places job-sharing means two people doing one job. At Social Security job-sharing means one person doing two jobs.

We have benefit authorizers at our processing centers who, at a point in the day when our calls reach a peak, turn to their telephones and pick up the lines so that the telephone service representatives can go to lunch. We are open on the line, a live person on the line, from 7 in the morning until 7 in the evening.

What we are finding is that from 7 in the morning until 9 in the morning and from 5 in the evening until 7 in the evening people are not calling, the assumption being that we are only open during business hours. So we have combined what we are trying to do with public service announcements, that you will see very shortly, which will say to senior citizens, essentially, have breakfast with Social Security. As you are having your orange juice and coffee, you can call Social Security. There is someone there to answer your call. Or we will show young people, who presumably are currently in the work force running with the sun rising over the Capitol with the voice-over saying, Social Security, we are up and running when you are.

The idea is to try to move people away from thinking that we are only there from 9 to 5; to make sure they understand that we also are there to serve them from 7 to 9 in the morning and from 5 until 7 in the evening.

It is a tremendous management challenge, Mr. Chairman, and frankly, not one that I would have volunteered for. But since it is here, we are wrestling with it, and I think we are going to get it under control.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Ms. King, thank you very much. I appreciate your testimony. We have a vote on the floor now. So, we will just end it here. I have some additional questions I will submit to you in writing.

Ms. KING. I would be happy to receive them, thank you, Mr. Chairman.

Senator HARKIN. And I understand Senator Cochran and Senator Specter have some questions also they will submit in writing.

Ms. KING. Thank you.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

SOCIAL SECURITY ADMINISTRATION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

CUTTING SOCIAL SECURITY TAX RATES

Question. Much discussion has occurred in recent weeks about whether the Social Security tax rate should be lowered now to reduce the use of the trust funds as a vehicle to disguise the size of the deficit? What is your view about the wisdom of this proposal?

Answer. I think it essential to preserve the integrity of the Social Security trust funds. To abandon the buildup now could:

- Expose workers and retirees once again to the uncertainties and anxieties about Social Security financing that prevailed before the 1983 amendments were enacted.
- Erase the strides we have made in restoring public confidence that the Social Security program is financially sound and can be relied upon to meet its benefit commitments today and in the future.
- Repudiate the widely held principle that the Social Security program should be changed only to serve Social Security, not Federal budget, objectives.
- Impose a heavier burden on future workers for supporting "baby boom" retirees.
- Signal to the American people that its leadership had lost hope of reducing non-Social Security budget deficits so that trust fund reserves could truly be saved.

SSI OUTREACH

Question. Conference report language encouraged you "to include a combination of direct services and contract service with organizations such as the existing network of area agencies on aging and the Administration on Aging."

To what extent has the Commissioner on Aging been involved in developing this outreach initiative, and what contract services are being utilized?

Answer. The Social Security Administration (SSA), the Administration on Aging (AOA), and the Health Care Financing Administration (HCFA) have signed a memorandum of understanding (MOU) agreeing to work cooperatively on various projects in fiscal year 1990; Supplemental Security Income (SSI) outreach falls under the umbrella of this MOU. We have had several discussions with AOA on the content and direction of the SSI Outreach Demonstration program. AOA is especially interested in the area of SSI outreach to the needy minority elderly and has established this as a priority area in its recent demonstration program announcement. We will continue to work together to coordinate outreach activities to the elderly.

SSA's SSI Outreach Demonstration program will award approximately 15 to 20 grants and cooperative agreements; SSA does not plan to contract out the outreach function. On February 2, SSA published in the Federal Register a notice requesting ideas from the public on the content of the priority areas for these grants and cooperative agreements. Based on the priority areas established, we plan to announce the program and request applications in early April with awards being made by September. The Outreach Demonstration program will target urban and rural areas of the country, English speaking and non-English speaking communities, and minority communities. In addition, it will focus on the elderly, the homeless and disabled children.

STAFF MORALE

Question. Commissioner King, last September you sent me the results of a survey showing that general morale of Social Security employees has declined, and indicated that many areas needed immediate improvement. That survey showed 74 percent of employees felt "often or very often overworked" and 38 percent stated that they did not have enough time to do a good job. Fifty-one percent described their morale as poor or extremely poor What specific steps are you taking to address the concerns of your employees?

Answer. The morale of SSA employees is extremely important to me and will be an ongoing priority. One of my major goals is to provide a work environment that ensures a highly skilled, motivated workforce dedicated to meeting the challenge of SSA's public service commitment. Employee polls consistently show that this dedication exists in the workforce; our job as managers is to provide an atmosphere in which that dedication can flourish.

I have directed that we identify field offices with the most critical staffing needs caused by downsizing. Then we will expedite the recruitment and hiring of new employees.

I have already expedited the allocation of critical production enhancing tools, such as personal computers and claims processing terminals in operating components, and I will continue these efforts. I am also ensuring that we give other forms of relief, such as needed supplies and training, to individual offices in order to facilitate a positive work environment for SSA employees and provide improved service to the public.

I have suspended all numerical performance goals. During the period of suspension, new goals will be developed that focus on my public service-oriented priorities.

Employees in SSA central office and other large work sites will soon have the option of enrolling their children in onsite daycare facilities. To further express my concern for the well-being of the families of SSA employees, an innovative, onsite eldercare facility is also being planned for SSA central office starting in early 1991.

I have established the position of SSA ombudsman, not to deal with the public, but to identify and propose solutions to systemic problems in the Agency.

On January 25, 1990 I signed a new 3-year agreement with the American Federation of Government Employees (AFGE) and I plan to meet with AFGE leadership on a regular basis to keep the lines of communication open between SSA and Union management.

I am developing ways to open channels of communication with all SSA employees as I believe this is critical not only to morale, but also for the effective and efficient overall performance of the Social Security Administration.

800 NUMBER TELEPHONE SERVICE

Question. What type of information is available on who calls and why?

Answer. Recent information indicates the reasons people call SSA's 800 number include:

• General inquiries	27%
• Social Security cards and questions	13%
• Interest in filing a claim	11%
• Medicare cards and questions	11%
• Change of address and direct deposit	10%
• Benefit estimates and verifications	7%
• Questions about the receipt of checks	6%

Question. Do you think people are calling more now because you have a toll-free 800 number?

Answer. Before the inauguration of 800 number service in October 1988, we did not have complete information on the number of calls attempted by the public to Social Security, and no information existed on the number of people who called local offices but were unable to get through. As a result we did not fully anticipate the strong demand for service that we have experienced since nationwide implementation of 800 number service in October 1989, and especially the demand we have experienced on peak days. Although we do not have any direct evidence of this, we think making SSA more accessible over the phone has created additional demand for service from SSA.

In addition, our call volumes are up this year because many of the publications we and the Internal Revenue Service mailed out last year--such as information concerning the amount of earnings subject to Social Security taxes, and the amount to be withheld from peoples' Social Security checks for Catastrophic Health Insurance--were rendered obsolete by legislative changes enacted late in 1989.

PEAK CALLING PERIODS

Question. When you look at the data on the volume of calls and busy rates, what jumps out at you is that everyone calls at the same time--at the beginning of the month, the beginning of the week and the middle of the day.

Have you considered increasing your capacity for these peak periods of time or getting people to call when the phones are less busy?

Answer. It is true that demand for 800 number service has been especially strong at the beginning of the month, when checks are issued, and on the first day of the week. During these periods of peak demand it sometimes has been difficult for the public to get through to SSA over the phone.

To provide additional staff to handle calls during peak demand periods, we established a second backup or "spike" unit in the Chicago Program Service Center. This unit consists of 130 benefit authorizers, employees who are fully trained in the Social Security program. These employees join employees from the Southeastern Program Service Center in Birmingham, who also are providing excellent assistance to the staff in the teleservice centers during peak demand periods.

Callers placed in queue after reaching a teleservice center are given a recorded message informing them that the best time to call SSA is before 10:00 AM or after 4:00 PM. SSA will launch a national public service announcement campaign in March encouraging the public to call our 800 number during the morning hours of 7:00 AM to 9:00 AM when call volumes are low. "Prime Time 800" will promote consumer attention to SSA's early hour service availability and will also increase public awareness of the many types of business that can be conducted with SSA over the telephone.

Question. Why don't you return to the practice of utilizing experienced field office staff to answer telephones?

Answer. The teleservice representatives currently answering telephones are trained to answer the vast majority of general inquiries and transactions requested through the 800 number service. Issues regarding pending actions and those of greater complexity are referred to the technicians in field offices for handling. Callers are provided with access to field office personnel on any issue if they express a preference in dealing with field office staff. We believe that this approach best utilizes experienced field office staffs in processing field office workloads and supporting the 800 number system.

ACCURACY OF TELEPHONE INFORMATION

Question. A year ago, your Agency found out that 24 percent of the responses given over the 800 phone system to questions about Supplemental Security Income (SSI) were incorrect. Have you been able to reduce this high level of misinformation about the SSI program?

Answer. The 24 percent SSI error rate was a finding of a special study conducted in October 1988, 2 weeks after the 800 service was implemented. The purpose of this study was to detect any early problems and it was, by design, not intended to be representative of all calls received by teleservice centers (TSCs). Assuming the role of the public, SSA analysts asked preselected test questions intended to identify complex technical policy areas in which additional training may be needed. Such questions were much more difficult than the average calls received on SSI.

To better gauge overall TSC performance, the study methodology was modified to monitor actual calls coming into the 800 number. This provides the means for measuring the accuracy of all types of inquiries, ranging from the routine to technical, complex issues. We are monitoring the TSCs on an ongoing basis. Because of the expansion of the 800 service and the establishment of the mega-TSCs it is necessary to create a new accuracy baseline. It will take 6 months of data gathering to create this baseline. The first 6-month period ends March 1990. Preliminary data for October to December 1989 show an overall accuracy rate for information that could affect payment or eligibility of about 97 percent; the SSI accuracy rate is about 93 percent. As noted, we need 6 full months of data gathering to establish a baseline for future comparisons.

Question. What can you do when you find out erroneous telephone information resulted in loss of benefits to the needy aged, blind and disabled people eligible for SSI?

Answer. Our primary interest is in preventing erroneous information from being provided to the public. To that end, we use several methods to obtain feedback on the correctness, completeness and responsiveness of the information provided by teleservice representatives--SSA special studies, service observation conducted by TSC management and routine, day-to-day observation of work performance/products. Data gathered are used as the basis for refresher training. This training is conducted on a regular basis to apprise staff of new procedures and to remind them of correct procedures for areas where deficiencies have been noted.

Effective December 19, 1989, section 10302 of Public Law 101-239, permits us to deem an application date to the date the person received incorrect information (or the first month the person meets all the requirements for entitlement, if that is later). Implementation of this law will provide greater assurance that people will not lose benefits because they received incorrect information from SSA staff.

Field offices (FOs) are currently maintaining lists of individuals who allege that they lost benefits due to receipt of misinformation, along with any documentation provided. Procedures for resolving these situations are being developed. When procedures are released to FOs, these individuals will be afforded the benefits of the legislation.

Question. What type of system do you have in place to regularly monitor the accuracy of telephone information, and what has it told you so far?

Answer. SSA has developed an ongoing system for measuring TSC accuracy by observing actual calls to the 800 number. Calls are monitored on a scheduled basis and data are gathered on the purpose of the call, the action taken and the accuracy of the response. The sample is targeted to provide statistically reliable data at the regional level on a 6-month basis. Smaller TSCs are monitored every other month while megasites are currently being reviewed each month.

In addition to monitoring calls, on a quarterly basis we contact a sampling of callers using the 800 number. The purpose of this survey is to obtain the public's perception of the 800 service. That is, are callers satisfied with the service and are we providing courteous service? The latest survey conducted in November 1989 indicated that 88 percent are satisfied with the service and 98 percent feel they are treated courteously.

Question. How do you use this information to improve accuracy?

Answer. We use a variety of sources to obtain feedback on teleservice representative (TSR) accuracy--studies by SSA's Office of Program and Integrity Reviews, service observation and routine day-to-day observation by managers. The teleservice centers (TSCs) use this information to target refresher training on a regular basis. The refresher training is conducted to keep TSRs apprised of new procedures and to advise them of the correct procedures involving identified problem areas.

Question. What training do telephone staff receive on complex Social Security laws to insure that they impart correct information?

Answer. Complex issues are referred to field offices. The TSR training course and the TSC Operating Guide cover the issues for which TSRs are responsible. Refresher training in problem areas is conducted as needed.

FUTURE OF THE 800 NUMBER

Question. What do you see as the future of the 800 number?

Answer. The 800 number service is an enhancement of SSA's service and a convenient option for the public in dealing with SSA. Both person-to-person telephone service and face-to-face service in local offices are required to provide the balanced service the public wants and deserves. SSA's 800 number service provides answers to general inquiries and allows the public to handle a large volume of simple transactions by phone, and we continue to see it serving those purposes in the future.

Question. Do you see teleservice centers replacing field offices?

Answer. No. The 800 number service was never intended as a replacement for field offices. SSA has had teleservice centers since the early 1970s. By October 1988 when the 800 number was offered to 60 percent of the country, there were 34 teleservice centers in operation serving 50 percent of the nation. The 800 number provided a single, easy to remember number for all callers and toll-free service to the 10 percent of callers who previously had to pay to reach SSA. The teleservice centers that had been taking the calls for many years continue to provide the service. Since that time, four large teleservice centers with over 1,000 teleservice representatives have been added to the 800 system to provide improved access when service was increased nationwide in October 1989.

Improved telephone service allows field offices to do their job better because high volume, simple workloads can be efficiently handled by the teleservice centers. This allows employees in field offices to better serve those who choose face-to-face service.

Question. How much is included in your budget for the 800 number, and is it sufficient to bring down the busy rate?

Answer. SSA's original workyear estimate for the 800 number service in FY 1990 was 3,400 workyears. This has been revised to 3,800 to 3,900 workyears based on current experience. We expect FY 1991 workyears to remain at least at this level.

To provide additional staff to handle calls during peak demand periods, we are reviewing the impact and resource requirements of additional backup or "spike units". Two such units have already been established in our program service centers in Birmingham and Chicago and are quite successful. We are looking to these units as a possible source for the additional staff necessary to handle periods of peak demand without increasing overall staffing at the TSCs.

In addition to the workyears which SSA will devote to the 800 number service there are other factors which we feel will enable us to bring down the busy rate. As SSA's TSRs become more experienced in the handling of incoming calls and training is directed to their specific needs we expect the volume of calls handled by each TSR to increase and the accuracy of information given to improve.

Additionally, we expect the number of calls related to the Medicare Catastrophic Coverage Repeal Act of 1989 to decline significantly by next year.

SSA currently has live 800 number service available from 7 A.M. to 7 P.M. 5 days a week. However, what we are finding is that from 7 A.M. to 9 A.M. and from 5 P.M. to 7 P.M. people are not calling, the assumption being we are open only during business hours. We are now planning a series of public service announcements which will encourage individuals who wish to contact SSA to call in these morning and evening hours when the volume of calls is not as high.

Question. Is bringing down the busy rate and improving your phone service a matter of money, management or technology?

Answer. Bringing down busy rates and improving phone service depends on a number of complex factors which include resources, management and technology. Many of these factors can be addressed through management initiatives and new technology. Certainly resources are a key factor, and the FY 1991 budget request includes additional resources to improve 800 number service. SSA is currently studying all of these factors and is committed to providing good public service through the 800 number service.

TELEPHONE ACCESSIBILITY

Question. When the Agency developed the "800" number system, it established a goal to keep the busy signal rate below 5 percent, put no more than half the calls on hold, and keep average wait time on hold below 60 seconds. Do you still intend to meet this standard for telephone accessibility?

Answer. We have established "bimodal" performance goals to measure telephone accessibility. Since SSA work traditionally peaks around the days when monthly payments are made and all offices (field offices and teleservice centers) have traditionally been busy at these times as well as on Mondays and Tuesdays, we have established "peak day" and "regular day" busy signal goals. The new goals will be achieved on an incremental basis by the close of FY 1992. A 5 percent busy rate goal is the regular day goal. A 20 percent busy rate goal for peak days has now been set. Having "bimodal" goals rather than a monthly average goal of 5 percent is more realistic and better measures the quality of the service that is being provided on the 800 number. Goals for the number of calls in queue and the average wait time are unchanged.

Question. How can you meet this standard without expanding staff or diverting employees from local offices?

Answer. SSA is evaluating the most effective ways to deal with the peaking workload demands which the Agency traditionally faces. We are reviewing the impact and resource requirements of additional backup units for these days. Two backup units, or "spike units," have already been established in our program service centers in Birmingham and Chicago, and they have been quite successful. "Spike units" consist of technical employees who can answer calls at their desks on peak days. Since they already perform technical work, minimal training is required and the required computer terminals are already available. There is an impact on the work that these employees normally complete, but we believe it is more cost effective to have these spike units serve only when needed in conjunction with full-time teleservice representatives than to depend exclusively on teleservice representatives. Technological improvements also are possible, and SSA will fully analyze and pilot any changes to insure that they indeed will provide improved public service.

ENROLLMENT GAP FOR SSI BENEFITS

Question. A longstanding problem facing the SSI program is the apparent gap between the number of individuals eligible for the program and the number of individuals receiving benefits, particularly for the elderly. What do you estimate the enrollment gap is for the elderly?

Answer. Estimates of aged participation in the SSI program range from 55 to 65 percent of those eligible. There could be as many as 1 million people age 65 or older who do not participate in the program who would be eligible for some benefits if they applied. While there may be differences in estimates of the true number of nonparticipants, there is some consensus as to their characteristics.

Persons who own their own homes or have earnings, pension income, or private health insurance are less likely to participate. Findings would indicate that the most needy eligible have higher participation rates. In fact, the ratio of total SSI benefits paid to total amount of benefits that persons are eligible to receive is closer to 83 percent.

Question. Do you believe there also is an enrollment gap for the blind and disabled?

Answer. Yes, we do believe that there is an enrollment gap for the blind and people with disabilities. Estimates of nonparticipation for these groups would be difficult to make. National surveys of low-income persons do not have a definition of disability that equates with the Social Security Administration's definition.

Question. Over the years, there have been a number of different approaches used to reach those eligible for SSI--for example, working with various advocacy groups and mass mailings to low income individuals. How would you characterize your approach to outreach?

Answer. Our outreach approach can be characterized as an effort to eliminate the barriers that discourage or prevent people from applying for and receiving the benefits for which they are eligible. As a first step, we identified the salient barriers to program participation and developed a comprehensive strategy to overcome them.

One real barrier is a lack of information about and understanding of program requirements and program benefits. Of course, people who do not know about the program or believe they would not be eligible will not apply for it. Others fail to apply because they connect program participation with the stigma of receiving "welfare" or they fear that they will be unable to successfully negotiate the application process.

Our strategy is based on a three-pronged approach to overcome barriers to participation by:

-- Providing information about program benefits and program requirements;

-- Working toward a more positive public perception of the program; and

-- Making the process of applying for SSI benefits as easy as possible.

Successful implementation of this strategy will involve partnerships and coalitions with public and private organizations that service potentially eligible people and share our goal of connecting them with program benefits.

SUSPENSIONS OF SSI PAYMENTS

Question. In November, the Social Security Administration issued a report that showed Supplemental Security Income benefits were incorrectly cut off for tens of thousands of the most vulnerable people in our society: the frail elderly, the blind, and disabled. In response to this report, you issued instructions in December to field offices reminding your staff that recipients must be given 30 days to respond to written requests, and follow-up contacts by phone or in person must be made before any action to suspend benefits.

Has sending out a notice to field offices been sufficient to correct this problem?

Answer. SSA has done more to correct this problem than sending out a single notice. The instructions we sent out, combined with a number of regional reminders and in-office training sessions, have made the field offices keenly aware that they must provide recipients proper notification, personally contact and give assistance to them when needed, and follow proper time schedules before taking any action to suspend benefits because of recipients' failure to comply with requests for evidence to support continued SSI eligibility or verify payment accuracy.

On December 20, 1989, field offices were issued listings of individuals whose benefits had been suspended for failure to respond or cooperate. They reviewed these cases and took necessary action to correct any improper payment suspensions. Field offices were reminded that all new suspension actions for failure to respond or cooperate must be reviewed and signed off on by operations supervisors. Increased awareness, combined with this extensive management review and attention, is ensuring that field offices are sensitive to the needs of Supplemental Security Income recipients and that they make no unwarranted payment suspensions.

Question. Is this an example of how overworked staff simply didn't have the time to personally follow up with SSI recipients as they should have?

Answer. Our staff is dedicated and hard working, and concerned with our beneficiaries. The problem is one of focusing too much on numbers rather than people. My recent action to suspend and reevaluate all numerical performance goals and develop a new set of goals that focus on my public service priorities should help to remedy situations like this.

Question. Now that you are launching a new effort to get more eligible people to claim their SSI benefits, are you confident you have sufficient staff resources to make sure they won't subsequently be thrown off the rolls by mistake?

Answer. You can be assured that no recipient's benefit will be improperly suspended because SSA did not provide the needed attention to the case. Our SSI outreach planning will include sufficient resources to process the resulting workloads.

REPEAL OF CATASTROPHIC HEALTH INSURANCE PREMIUMS

Question. Although Congress repealed Catastrophic Health Insurance supplemental premiums effective January 1, 1990, we understand you have not been able to adjust Social Security checks in time, and will therefore continue withholding premiums for several months into 1990.

Describe the efforts you have made to speed up premium refunds owed to millions of Americans due to repeal of Catastrophic Health Insurance. Why will it cost $45 million to process refund checks?

Answer. I am pleased to report that SSA is on schedule to have all monthly Social Security payments corrected for the May 3, 1990 checks, to reflect the repeal of Catastrophic Health Insurance (CHI). In addition, the first of two refunds, to be issued to beneficiaries to compensate for having CHI premiums deducted from their checks for 4 months after repeal of the program, were issued before the end of February 1990.

SSA has given implementation of the repeal of catastrophic coverage top priority and has made every effort to make the premium adjustments as quickly as possible, without jeopardizing timely receipt of basic monthly Social Security benefits. We have redeployed systems staff to concentrate as many people as possible on the project, and we have provided resources for extended overtime to get the job done. As a result, the project is moving along successfully, on schedule.

I convened a panel of outside experts to meet with SSA's systems staff to ensure that our planning was on target. Because of the importance of timely refunds of excess premium deductions, a special payment process, consisting of two refund checks to be issued to beneficiaries in February and in April 1990, was developed at the recommendation of the outside panel. By February 26, 1990 the initial set of refund checks had been issued on time, as scheduled. By the end of April 1990, the second set of refunds will be issued, which will fully compensate for all underpaid Social Security benefits due to excess premium deductions; and corrected payments will be issued on May 3, 1990. In addition, I have assured the public through direct contact, recorded message and written notices that the premium adjustment and refund process is being carried out as quickly as possible, and that the May benefit check will be in the corrected amount.

We estimated that the cost of implementing the premium change would be about $45 million, to be funded by a transfer of funds appropriated to the Health Care Financing Administration in FY 1990. The principal costs include increased telephone and field office inquiries, additional overtime for systems programming, postage costs, and manual processing of cases excepted from the automated systems.

Question. Why does it take so long to adjust the Social Security Administration's computer programs?

Answer. Each year the Social Security benefit amounts are adjusted based on changes in the cost-of-living. In addition, the law mandates adjustments to the Medicare Part B (SMI) premium, which is the monthly amount that the beneficiary pays for Part B Medicare.

Both of these changes are made with the January Social Security checks. Therefore, one set of computer software is used to calculate and implement both of these changes. By combining these operations, the software can apply the "hold harmless" provision of the law. This provision requires that no beneficiary's total check be reduced at the time of the benefit rate increase to less than it was the previous month because of the application of the benefit rate increase and the Medicare premium adjustment.

This software must be absolutely accurate with an automation rate of close to 100 percent so that there is no delay in getting the January payments to all 39 million beneficiaries. Therefore, SSA takes extreme care to guard against potential errors and makes sure each of the 220,000 lines of software performs flawlessly. Many months are devoted to testing and validating the software prior to the actual receipt of the benefit increase and Medicare premium increase rates. Even though there is a flat percentage rate for the benefit increase, there are 230 possible Medicare premium amounts due to variations in rates and penalties. The software is validated further with the actual rates.

The Department of Treasury requires approximately 5 weeks to print the checks (and make direct deposit payments) so that they can be at the post offices for delivery on the third of the month. Therefore, SSA began sending payment tapes to Treasury on November 29, 1989 (for the January 3, 1990 checks). In order to have these payment tapes ready to send to Treasury, SSA had to run the software to calculate the January check amounts on the weekend of November 18, 1989. Given these constraints, a legislative change enacted after November 18, 1989 could not be reflected in the January 1990 payments.

In order to change the Medicare premium withholding rate SSA must write entirely new software, test and validate this new software, run it in SSA's computers and then transmit the payment tapes to the Treasury. The earliest SSA can complete this work is mid-March, which, given Treasury's lead-time requirements, means the earliest the checks can be corrected is May 1990.

Question. What improvements can be made to give your computer systems greater flexibility to quickly respond to future legislative changes?

Answer. It is difficult to respond in general to this question because legislation could affect many different areas of our automated processes. Specific information on timeframes would depend upon the complexity of the legislation and the areas most affected by it.

We have been making a significant effort to modernize and improve our computer systems to make them less complex and easier to maintain. We believe that these efforts will, over time, greatly improve the flexibility of our automated systems. Among the things that we are doing are the following:

- We are documenting and will be maintaining the specia software that we developed for the repeal of catastrophic coverage which enables us to implement a change in the premium amount without a simultaneous benefit rate increase. The unavailability of such software was, of course, one of the factors which inhibited our ability to swiftly respond to the repeal.

- As we modernize our software, we will be simplifying the logic wherever possible and consolidating similar processes to the degree possible to reduce the number of specific places that our systems would have to be modified to accommodate legislation affecting benefit rates.

- We will be continuing our efforts to better structure and organize our computer programs to make them easier to understand and maintain. In 1988, only about 30 percent of our software was classified as being well-structured. (Well-structured software is one of the primary factors in enabling changes to be made easily.) By early 1990, we had improved our software to the point where about 60 percent would be classified as well-structured. Continuation of these efforts will make our software more flexible and easier to modify.

- We will continue to explore and implement automated tools and processes to assist us in the testing and validation of our software. In processes which are the size and complexity of those at the Social Security Administration, it is absolutely critical that changes be implemented without introducing error. Even a small error can have catastrophic effects. Testing and validation are the largest factors in the lead time involved in implementing the repeal of catastrophic coverage.

However, even with improvements to the computer systems, it will still require lead time to implement changes to Social Security check amounts. Time is needed to make the software changes. Thorough testing and validating of the software is necessary to ensure that accurate payments are made. Then, Treasury requires approximately 5 weeks for its operation (including making direct deposit payments, as well as printing checks and distributing them to the post offices for delivery on the third of the month).

BENEFITS TO ILLEGAL ALIENS

Question. The Inspector General's Office estimated that Social Security benefits paid to illegal aliens exceeded $35 million in fiscal year 1988. By the year 2032, the Inspector General estimates illegal aliens would receive payments ranging from $1.8 to $5.4 billion annually.

I have co-sponsored legislation (with Senator Exon) to put a stop to this practice. Do you endorse legislation to prohibit Social Security benefits to aliens who have worked illegally?

Answer. The Administration has not established a formal position on this legislation, S.358. Within the Department of Health and Human Services, we are examining the recommendations of the Office of the Inspector General, as well as other related policy issues, such as the respective roles of the Social Security Administration and the Immigration and Naturalization Service in enforcing immigration laws.

RECONCILIATION OF WAGE RECORDS

Question. According to OMB, employee earnings records kept by the Social Security Administration show $58.5 billion less than IRS records indicate. This means that wage earners may be deprived of their fair share of Social Security benefits. Tell us what is being done to reconcile your records with IRS.

Answer. For tax years (TY) 1978 through 1988, SSA identified the discrepancies in which more earnings were reported to IRS than to SSA and corresponded with employers to resolve the differences. If the employer did not respond to the first request, a second mailing was made. For TY 1978 through TY 1986, SSA also attempted telephone contact for employer discrepancies that were for $500,000 or more.

Reconciliation for TY 1978 through TY 1983 has been completed. We anticipate that the cases for TY 1984 through TY 1988 will be virtually completed by October 1990, at which time we will be processing reconciliation cases on a completely current basis.

For TY 1985 and TY 1986, SSA turned over the unresolved telephone cases ($500,000 or more) to IRS for IRS to attempt to resolve. Beginning with TY 1987 per an agreement with IRS, SSA turned over the balance of TY 1987 unresolved cases for IRS to work.

Question. Why is it that Social Security records seem to have missed such a large volume of earnings records?

Answer. There are many factors contributing to the missed records. Most are attributable to poor employer reporting practices. Some of these include: (1) employers not using the same Employer Identification Number (EIN) when reporting to both SSA and IRS; (2) multiple use of EINs due to mergers, acquisitions, consolidations of one company with another and failing to show all EINs used for the company in that year; (3) some firms go out of business or go bankrupt and neglect to file Form W-2 (Wage and Tax Statement) with SSA; (4) some employers incorrectly send W-2s to the IRS or to States; (5) many companies file late; (6) some employers fail to balance W-2s with the summary Form W-3 (Transmittal of Income and Tax Statements); (7) in many instances, service bureaus are submitting wage data for employees to SSA that are prepared at different times from the Form 941 (Employer's Quarterly Federal Tax Return) submitted to IRS, and there is no effort to balance the four quarters' of Form 941 totals to the W-3s; and (8) 10 percent of magnetic media wage reports require resubmittals because they are incorrectly formatted.

Question. What is being done to minimize discrepancies from IRS records in the future?

Answer. SSA has taken on many initiatives to minimize discrepancies. Included in these are: (1) Special emphasis has been placed on educational programs and seminars for employers to increase public awareness of reporting responsibilities. In FY 1989, 423 joint IRS/SSA seminars were held. Also, SSA has reached out to over 50 percent of employers with instructional materials. (2) SSA is working with IRS to identify late filers, employers who file paper in lieu of magnetic media reports, and employers who file using improper forms, in order to assess penalties on employers for these infractions. (3) SSA introduced a Personnel Earnings and Benefit Estimate Statement (PEBES) in 1988. PEBES provides workers with a year-to-year record of their earnings as posted to SSA's records. (4) SSA is working with IRS to modify the W-3 to require employers to certify to SSA that the amounts reported to IRS on 941s agree with amounts reported to SSA. (5) SSA has developed software standards and edit criteria for use by employers and others in the preparation and submission of annual wage reports to SSA. These standards are voluntary but have been received favorably by the private sector. They have built-in checks and balances to ensure equal reporting to SSA and IRS.

STAFF FOR PROCESSING DISABILITY APPEALS

Question. In GAO's December 1989 report concerning conflicts between SSA management and its administrative law judges (ALJs), it was reported that staff shortages among ALJs and field support staff had contributed to delays in handling appeals. It was also reported that about two-thirds of the law judges cited low morale in their offices. Has your fiscal 1990 hiring freeze impacted on staffing levels and backlogs?

Answer. On November 1, facing sequestration and a budget cut of more than $100 million, we took steps to significantly reduce FY 1990 spending. These steps included a freeze on external hiring. This has resulted in a loss of ALJs and support staff during the last 3 months. This staffing reduction has contributed to an increase in the hearings pending during the first 4 months of FY 1990. With the threat of sequestration now eliminated, the Office of Hearings and Appeals (OHA) was given a limited exception to the hiring freeze to replace their most critical losses within available funding levels.

Question. How many administrative law judges are needed in fiscal year 1991? What level is expected to be on board by the end of fiscal year 1991?

Answer. SSA estimates that it will need 764 ALJs on duty by the end of FY 1991 and this is consistent with our current plans.

Question. Do you believe the staff resources in the Office of Hearings and Appeals will be sufficient to improve timeliness?

Answer. Due to the funding and hiring constraints that existed at the beginning of FY 1990, OHA will only be able to maintain current pending levels for hearings in FY 1990. However, the President's FY 1991 budget request does provide sufficient resources for OHA to increase ALJ and support staff levels, and this would allow OHA to reduce the level of hearings that are pending in FY 1991.

SURPLUSES IN SOCIAL SECURITY TRUST FUNDS

Question. The Social Security system has been and is expected to continue generating large surplus funds in the near future. Does this mean that the Social Security tax will be higher than necessary?

Answer. Payroll taxes that are currently increasing the trust fund reserves will be needed in the 21st century when the "baby boomers" begin to retire. By that time there will be only two workers paying into the system for each individual who will be receiving benefits. The current relationship is about 3 to 1. The present payroll tax structure is expected to provide sufficient revenue to pay benefits and other expenses until shortly before the middle of the next century.

Question. Are these surplus receipts being used to finance other activities of the Government?

Answer. The law requires any income to the Social Security program that is not needed for current program expenses to be invested in some form of United States debt security. This is true for all federally-managed trust funds. The Government then uses the proceeds of these investments to reduce the amount which it must borrow from other sources.

REMOVING TRUST FUNDS FROM DEFICIT CALCULATIONS

Question. There is considerable interest in Congress in taking Social Security out of the budget calculation for purposes of Gramm-Rudman-Hollings deficit reduction. What is the Administration's position on doing this?

Answer. The Administration is committed to preserving the fiscal integrity of the Social Security program and maintaining budget discipline. The 1991 Budget proposes a procedure to protect Social Security and balance the non-Social Security portion of the budget. This proposal is consistent with the view that Social Security should not be used to finance other Government spending.

Question. Is there greater justification for doing this for Social Security than other trust fund programs?

Answer. As Commissioner of Social Security it is not my position to speak for other trust fund programs.

IOWA SOCIAL SECURITY HEARINGS AND APPEALS OFFICE

Question. The Senate report accompanying the FY 1989 Labor-HHS-Education appropriations bill, directed the Social Security Administration to provide at least one additional decision-writer as well as word processing and computer equipment to enhance efficiency in processing appeals of disability claims in Des Moines, Iowa.

What action has been taken to better meet staffing and equipment needs of the Des Moines office?

Answer. The Des Moines Hearing Office recently received clearance to recruit office support staff deemed critically needed.

The office will be hiring one additional clerk typist and one additional staff attorney in the immediate future.

An additional standard personal computer has been delivered to the Des Moines office and another, a portable model, will be delivered soon. This will bring the total number of personal computers assigned to the office to seven.

Question. What progress is being made to reduce the backlog of appeals of disability claims in Region VII, which includes the State of Iowa, compared to the national average?

Answer. Nationally, the average number of cases pending per Administrative Law Judge (ALJ) has steadily increased during fiscal year (FY) 1990, rising from 224 cases per ALJ at the end of October 1989 to 230 at the end of January 1990. At the same time, the backlogs in Region VII and in the Des Moines Hearing Office have diminished--in January 1990, the average pending per judge in the Kansas City Region was 224 cases as compared to 228 in December 1989; during the same time period, the average workload per ALJ in Des Moines dropped from 201 to 192.

In January 1990, ALJ disposition rates for Region VII and the Des Moines office improved significantly over the first quarter of the fiscal year. While the average rate for January increased by two cases per judge nationally (from 35 to 37) over the first quarter average, the average rate for Region VII ALJs improved by more than seven cases per ALJ (from 31 to 38), and the average for ALJs in the Des Moines office increased by nearly 13 dispositions (from 29 to 42) per judge.

DEMONSTRATION PROJECTS WITH DISABILITY CLAIMANTS

Question. In 1984, the Congress required the Social Security Administration to conduct Personal Appearance Demonstration projects in 10 States to test the efficiency of face-to-face interviews with disability claimants by State claims examiners before they denied or terminated benefits. The projects were late getting started. Also, GAO reported in April 1989, that selective face-to-face interviews with certain claimants could reduce appeals. Have the demonstration projects been completed?

Answer. The ten demonstration States completed their activity in March 1988. The States that processed initial claims were Arizona, Michigan, Mississippi, New Mexico, and Washington. The States that processed continuing disability review claims were California, Florida, Maine, Missouri, and New Jersey. In total nearly 40 thousand claims were involved in the project.

Question. Have you completed your study of the project?

Answer. We are now completing our evaluation of the study. The State-level field data gathering phase of the project was completed in March 1988. We allowed for an additional 6 months to cover all possible appeals of the claims completed through March 1988. The compiling and data matching phases of the project were completed in October 1989.

The Social Security Administration requested the Office of Inspector General (OIG) to conduct an independent evaluation and client satisfaction survey. OIG presented a draft of their client satisfaction survey on January 18, 1990. OIG's final independent report on the demonstration's claims data is expected in the third quarter of FY 1990.

Question. What have you concluded regarding the project?

Answer. OIG's client satisfaction survey report, presented to SSA for comment in January 1990, found that the claimants that took advantage of the face-to-face interview liked the process and had a high comfort level with the interview. This anecdotal survey, which was conducted during 1987 when the project was in full swing, gathered reactions from 66 claimants and 69 Disability Determination Services (DDS) employees, including disability examiners and managers. The disability examiners interviewed by OIG also liked the process and thought it was helpful in formulating the final decision. DDS managers were concerned that the face-to-face interview process would negatively affect DDS ability to improve productivity and reduce staff. We are now carefully analyzing the project's extensive decision outcome data, and we expect that the report will be completed this year together with OIG's independent report.

MEDICAL CONSULTATIVE EXAMINATIONS

Question. The Social Security Disability Benefits Reform Act of 1984, Public Law 98-460, enacted October 9, 1984 requires the Secretary to issue regulations to establish standards for medical consultative examinations. These regulations were to be issued no later than 180 days after the date of enactment. Why has it taken so long to issue the required regulations?

Answer. I sent the final regulation to the Secretary for his approval early in February. This regulation is lengthy and complex. In addition to SSA's consultative examination policies that Congress accepted, it includes revised medical evidence of record (MER) requirements and some consultative examination management changes that the General Accounting Office has recommended. In addition, the publication of the notice of proposed rulemaking and the related draft operating instructions for the State Disability Determination

Services generated extensive comment from the States, all of which had to receive due consideration before the regulation could be made final.

Question. Despite the lack of final regulations, have any of the Act's provisions regarding consultative examinations been implemented? If so, which provisions?

Answer. The Act's provisions regarding consultative examination policy largely restated SSA's existing policy and procedures in this area. SSA had already set guidelines for when the States should purchase consultative examinations and what kinds should be purchased. In addition, SSA had developed and published consultative examination management and review instructions in its Program Operations Manual System several years before the 1984 amendments were enacted. As a result, the 1984 amendments made no substantive changes in consultative examination management policy.

Question. What provisions have not been implemented and why not?

Answer. SSA had already implemented all of the consultative examination provisions contained in the 1984 amendments before they were enacted.

SOCIAL SECURITY TAX INCREASE

Question. Social Security payroll taxes went up this January from 6.06 percent to 6.2 percent, and are expected to generate surpluses, monies not needed to pay benefits, in excess of $50 billion this year. What is your comment on proposals that this tax hike be repealed, returning the Social Security program to a pay-as-you-go system? Why should Social Security surpluses be used to offset the Federal deficit?

Answer. Repealing the 1990 tax rate increase and going back to pay-as-you go financing of Social Security could erode public confidence in the program and expose current and future beneficiaries once again to the uncertainties and anxieties about the program that prevailed as recently as early 1983. Under the tax rate schedule enacted in 1977 and the program reforms enacted in 1983, the Social Security program was put back on sound financial footing, and public confidence in the program began rebuilding. The growing trust fund reserves are not "surpluses;" the scheduled reserve buildup has a specific purpose--to help finance Social Security benefit payments to today's workers when they reach retirement.

Moreover, the Social Security tax rate increase that became effective on January 1, 1990, is important to the near-term financial soundness of the program. The trust funds had reserves of about $188 billion at the beginning of 1990, an amount equivalent to about 9 months' benefit payments. Most experts agree that reserves of 1 year to 18 months' benefits are necessary to protect the program against adverse economic conditions such as we experienced in the late 1970's and early 1980's. Reserves are not expected to grow to the equivalent of 18 months' benefits before 1993.

The Administration is nevertheless concerned that, under the Gramm-Rudman-Hollings calculations, annual increases in Social Security trust fund reserves have the effect of masking a substantial part of the deficits in the non-Social Security part of the budget. In response to this concern, the President's budget for FY 1991 includes an initiative, the "Social Security Integrity and Debt Reduction Act of 1990," which would both preserve the integrity of the Social Security trust funds and require responsible steps to bring the non-Social Security part of the budget into balance.

EXPANDING COMPUTER CAPACITY

Question. In FY 1989, the Social Security Administration awarded two contracts for $12.8 million and $8.3 million, to increase its computer capacity. During fiscal year 1990, the Agency plans to award two additional contracts to increase computer capacity to support expanded services. Although the Social Security Administration has yet to put a capacity management program into place, it still continues to acquire additional computer capacity.

Given that the Social Security Administration has continued to acquire computers, what has been done in the interim to assure that these acquisitions during this period--January 1989 to the present--have been fully justified?

Answer. SSA has in place a sound and highly professional capacity management program, which has been developed and implemented over the past 3 years. This program was designed and implemented with the support of a leading capacity consultant (Booze, Allen and Hamilton) and it has been extensively reviewed by other independent consultants, by GAO and OIG, and it has been found to be sound and reliable.

An exhaustive 1988 review by Systemhouse, Inc. and International Systems Services Corporation (ISS) found SSA's capacity management to be fully up to the standards prevailing in the industry. Notwithstanding this, SSA recognized there was room for improvement, and we have implemented all of the major recommendations for improvement made by all reviewing authorities and consultants. We now have a capacity planning process which compares favorably to any the industry can offer.

SSA has used this capacity planning process to fully justify and support all procurements since January 1988.

Question. When do you expect to complete and implement the scheduled improvements to capacity management activities?

Answer. All of the major recommendations from SSA's capacity consultant (over 90 initiatives) were fully implemented by December 1989.

SSA now has a comprehensive capacity planning process in place, which is used to project capacity requirements and justify procurements. However, improvements and refinements to that process continue. SSA is committed to remaining as an industry leader in capacity planning.

PLANNING AND BUDGETING

Question. For the past 2 years the Social Security Administration has been developing an agencywide strategic plan to provide overall guidance for all organizational activities, including computer systems modernization. However, this committee has found the plans to lack detailed comprehensive descriptions of its computer modernization expenditures. Consequently, the committee has found these plans to be of little use in evaluating Agency requests for increased computer spending authority.

Why has it taken so long for the agency to develop an adequate comprehensive computer modernization plan?

Answer. In 1983, SSA developed a comprehensive systems modernization plan, the SMP, to avert an impending crisis in its ability to deliver basic services. The SMP was necessary to move SSA from a crisis state into a position of systems health, and it did so. However, it became clear to SSA that an Agency strategic plan needed to be in place to drive all of the Agency's activities, including systems support activities, and that, conversely, a systems plan could not and should not be used to drive the actions of the Agency.

In 1988, SSA published its first such Agency strategic plan (ASP), 2000: A Strategic Plan. It was intended to provide a clear vision of SSA's future which could serve as the basis for planning for a full range of Agency functions. The ASP was a good first attempt at strategic planning, but it did not provide the complete guidance necessary to allow SSA to develop solid transition plans in the information systems arena. While SSA was successful at identifying what the Agency needed in the short term to maintain itself and move toward certain discrete elements of the future vision, the planning process was not completed.

Recognizing these defects in the planning process, we decided to renew the strategic plan. The new plan will include supporting architectures that can be used to develop a clear connection between SSA's vision for the future and its present funding needs, both in the information technology systems (ITS) and non-ITS arenas. SSA has just begun to renew the strategic plan.

The systems components at SSA have not stopped planning or producing while waiting for a new strategic plan to be developed. However, the plans which have been made are relatively short term and highly flexible, to ensure that the systems activities being performed now do not commit us to a course which will be in conflict with the new vision of SSA's future.

Question. Considering GAO's finding over the past decade concerning the Social Security Administration's problems in computer planning, have you established any measurable standards to assess progress in computer modernization planning and budgeting?

Answer. SSA has established measurable standards in a wide variety of systems-related areas. Notably, SSA regularly uses User Service Agreements, in which standards of systems performance are agreed upon by the user and the provider of systems support services. The meeting of the standards is closely monitored. SSA has established standards for software development in its software engineering technology and routinely evaluates each software product against this standard. Just a few examples of other standards which have been developed to assess modernization progress include the following:

- Rate of availability of SSA systems to field office users.
- Systems response time.
- Abnormal job end (ABEND) rate.
- Capacity utilization rate.
- Time to complete annual wage report postings.

In addition, project and program plans are still being developed, and success in meeting scheduled milestone dates and expected resource usage are closely monitored. In summary, therefore, SSA has already taken a series of steps to establish and measure compliance with standards in its systems-related activities. We expect to identify other standards once the Agency establishes its strategic-level service requirements as part of the Agency strategic plan renewal process.

WAGE REPORTING

Question. Any wage reports that SSA cannot identify as belonging to a valid Social Security account are recorded in its Suspense rather than Master Earnings File. Historically, about 3 percent of each year's wage reports have been recorded in the suspense file. Former Commissioner Hardy had emphasized the need to reduce the growth of postings to the file. What progress has been made in reducing growth in this file and what new actions are being taken or considered?

Answer. Currently, about 3 percent--6 million--wage reports with invalid names/numbers are filed with the Social Security Administration (SSA) each year. SSA expends $1.5 million and 100 workyears to validate these reports, using a variety of internal checks and correspondence to employees and employers. These efforts reduce the invalid reports to 1.5 percent--3 million--of all wage reports filed with SSA. As a byproduct of these efforts, an additional quarter of a million wage reports from prior years are also validated using new information provided by employees and employers in response to such correspondence. In the past year SSA has obtained the Internal Revenue Service's (IRS') cooperation in adding messages to IRS publications and form instructions for employers about the importance of correctly recording and reporting employees' names and Social Security numbers. SSA has provided the same message in its own public information activities, while also encouraging employees to request earnings statements to ensure that SSA has correctly recorded all the wages earned.

An intercomponent workgroup has been designated to identify other ways to reduce growth in the Suspense File, and their recommendations are expected shortly. Among the possible approaches the workgroup is considering are ways to:

- Work with IRS on mutual name/number matching problems to ensure SSA receives all appropriate identifying information from IRS records that SSA needs to validate wage reports.
- Reinstate the National Electronics Reinstatement Process. On a trial basis, SSA invited employers having large numbers of invalid reports recorded in the Suspense File for prior years to recheck them to their payroll records and provide corrected information so the reports can be properly credited. This process was very effective and resulted in a reduction in the number of items in the Suspense File.
- Encourage problem employers who consistently report large numbers of invalid name/numbers on wage reports to improve their reporting.
- Improve SSA correspondence sent to employers and employees about invalid names/numbers on reports to encourage better reporting in the future

Question. Many of these wage reports that end up in the Suspense File each year are received from the same employer each year. What is done or can be done to get these employers to stop repeating these same errors each year?

Answer. Last year SSA used special telephone and mail contacts with employers who had large numbers of invalid name/numbers, to validate their reports. This is still being done on a trial basis and it is too early to tell what impact such contacts will have on future reporting by these employers. As mentioned above, the Suspense File workgroup is considering ways to monitor problem employers and encourage them to improve their reporting practices. However, recent enactment of the Omnibus Budget Reconciliation Act of 1989 has provided IRS for the first time the authority to penalize employers who file incorrect wage reports. Effective use of this authority could go a long way toward reducing invalid wage reports. SSA will begin negotiations shortly with IRS on how this penalty authority should be used to encourage better reporting.

QUALITY OF SERVICE TO THE PUBLIC

Question. Union complaints and other surveys of Social Security Administration personnel indicate that morale is bad and that field personnel believe they are unable to adequately serve the public because of staffing reductions amidst rising workloads. The Agency has repeatedly emphasized its recent efforts to improve quality of service to the public. Would you tell the committee what major changes you have made during the past year and what you plan for the coming year?

Answer. Providing outstanding public service has always been and will continue to be the primary focus of the Social Security Administration. We pay very close attention to our client surveys--to the trends of our public inquiries and other barometers of our service. Our ongoing refinements to the national 800 telephone number and the establishment of a new Supplemental Security Income outreach program are major initiatives undertaken to attend to public service needs.

I believe our network of field facilities does offer generally excellent service and service choices for the American public at the present time. We continue to be under pressure to provide high quality service with limited resources, and I am initiating several actions intended to continue our service levels.

I will be providing additional interviewing staff to selected field facilities where the need is the greatest. One long-term result of this effort will be an enhanced SSA presence outside of the immediate confines of an SSA field office, because the need for additional field representative positions is one of the criteria that will be used in providing new hiring authority. Our objective is to better serve the disadvantaged elderly and disabled who, for whatever reasons, cannot visit a field office yet prefer face-to-face contact when dealing with Social Security.

I have made it very clear that service to the public is of utmost importance to me. I have reaffirmed and reinforced that goal in any number of decisions--assuring that we act beyond reproach in our decisions affecting our public; assuring that we reach out to those needing our service; assuring that our operational goals stress service, as well as productivity and these management objectives.

MAKING SSA INDEPENDENT

Question. What is the Administration's position about making SSA independent of the Department of Health and Human Services?

Answer. The Administration strongly opposes taking SSA out of the Department of Health and Human Services and making it an independent agency.

To carry out its mission of providing effective and efficient public service, SSA must stay clearly focused on that goal; be well managed, motivate and meet the needs of its employees, and obtain sufficient resources. This has been and can continue to be done within HHS. Independent agency status would not make the task any easier and, indeed, is squarely against recognized concepts of good management.

Further, separating SSA from HHS would undercut the President's role as manager of the executive branch, weaken SSA's important links with health and social services programs for the aged administered by other HHS agencies, and eliminate many administrative economies inherent in a large government department.

Question. What is your position, as the present Commissioner of the Social Security Administration?

Answer. I agree wholeheartedly with the Administration's position. The only tangible effect of an independent SSA would be to decouple the program from an interdependent service delivery system already established and working well at HHS. Right now, for example, our 1,300 Social Security field offices across the United States serve older Americans as "one-stop shops" to get information on Social Security, Medicare and other programs like Meals on Wheels. That convenience may disappear if SSA were made an independent agency. Moreover, as the baby-boom generation ages, the need for coordinated services for the elderly will increase rather than decrease.

Given the importance of Social Security to so many Americans, I believe it would be a serious mistake to group Social Security with dozens of other small independent agencies in Washington, D.C., with no voice at the President's Cabinet table. I would argue that without the representation the program currently enjoys at the highest levels of government, Social Security would become more, not less, vulnerable to political changes.

Question. What would be the cost implications of creating an independent agency?

Answer. As a component of HHS, SSA's share of the cost of Department operations is paid from its administrative appropriation or directly from the Social Security trust funds. If SSA were made an independent agency and chose to provide all those services internally, ongoing costs should be approximately the same but startup costs could be considerable for establishing, for example, a new personnel/payroll system.

REPRESENTATIVE PAYEES

Question. There have been a number of major incidents of abuses in the past couple of years in the handling of Social Security checks by people assigned to administer the funds on behalf of Social Security clients. What has been done to curtail these incidents?

Answer. Shortly after I became Commissioner, I emphasized to all Social Security employees the urgency in finding qualified payees and reaffirmed our obligation to ensure that beneficiaries do not see their limited resources slip away. I am very strongly committed to using all of the means at SSA's disposal to find the best possible representative payees for beneficiaries who cannot manage their benefits.

We believe that one of the best ways to protect beneficiaries who need a representative payee is to identify additional sources of qualified payees. Thus, we are working with the American Association of Retired Persons, United Way, and other organizations to develop voluntary payee projects.

We also are placing increased emphasis on ideas developed by local Social Security offices for finding qualified payees. To aid our representative payment outreach efforts, we are preparing a video presentation showing the positive aspects of representative payee volunteerism. It will be distributed to our field offices for use in community activities.

We are in the process of changing appropriate forms and procedures to elicit more information about payee applicants' qualifications and to more intensively monitor persons who are payees for several beneficiaries. Additionally, interested parties are working with us to test a process in which SSA would screen payee applicants based on criminal records and credit data available to States.

Finally, we are developing a comprehensive representative payee data systems that will capture a full range of representative payee information needed to screen payee applicants more effectively, enhance monitoring of the accounting process, and produce statistical data.

Question. Do you believe that legislative measures now pending in the House and Senate to reform representative payee monitoring would be helpful?

Answer. We strongly oppose any proposal to allow nonprofit organizations to charge beneficiaries fees for representative payee services. Those who would be charged a fee are likely to have very limited income and resources. We think that people and organizations with a personal interest in the beneficiary's welfare and without financial motivation would better serve the beneficiary's needs. We are confident that our efforts, combined with the support of national organizations that have agreed to help, will result in sufficient qualified payees without imposing any costs on the beneficiary.

We generally support the objectives of other representative payee proposals either included in last year's House budget reconciliation bill or approved by the Senate Finance Committee during the Senate budget reconciliation process. However, we believe that some of these proposals are unnecessary because they are reflected in current policy. Also, we are concerned that some of the proposals, in an effort to solve specific problems, are so restrictive that they will deny us the administrative flexibility we need to be responsive to beneficiaries' needs in individual cases.

Question. Would they greatly increase your staffing requirements?

Answer. Most of the representative payee legislative proposals under consideration reflect SSA's current policies or planned activities. Thus, they would not significantly increase staffing requirements.

800 NUMBER TELEPHONE SERVICE

Question. Concerns have also been expressed that the 800 system may not be the right service delivery approach for many situations and that field offices could provide better service. What are your views on this?

Answer. Since the early 1970s, the public has been using the telephone more and more to conduct Social Security business, and currently over 50 percent of Social Security work is completed by phone. SSA's 800 number service has always been viewed as an enhancement of public service and not a replacement for field office service. Face-to-face service in field offices remains an option, and we fully agree that there are situations, especially those involving complex issues, in which field offices can provide better service. Many general inquiries and simple transactions can be conveniently handled by telephone.

Complex actions continue to be completed through the local field office. For example, while appointments are made for filing claims through the 800 number service, claims are actually taken by claims representatives, by phone or in person, in field offices. Many complex overpayment and SSI issues also are handled by local offices, and procedures for teleservice representatives state that such issues are to be referred to field offices.

Question. Have you made any changes to the 800 system in this regard, and do you have any changes currently under consideration?

Answer. Yes, we have made some changes. If the caller wants to deal with the local office directly on any matter, I have directed that the local number be provided by the teleservice center representative. It was never intended that the 800 number service would handle all of the complex issues better handled in field offices. The nationwide phone service is intended to serve as an entry point for contact with SSA, and many simple actions can be handled quickly and conveniently while the caller is on the phone. When an issue can be handled better by the local office, arrangements are made to have that office contact the caller.

UPGRADED EARNINGS AND BENEFIT STATEMENTS

Question. SSA has received a lot of positive publicity on its upgraded earnings and benefit statements (PEBES) that it provides to persons now at their request.

From an operational viewpoint, has there been any positive benefit from the project beyond the public relations? Basically, to what extent has the use of these statements led to the identification and correction of errors in the earnings records?

Answer. Fiscal year 1989 was the first full year of implementation of the Personal Earnings and Benefit Estimate Statement (PEBES). During that time, SSA experienced a 40 percent increase (from 128,000 to 180,000) in the number of earnings disagreements identified and corrected. This increase is attributable directly to PEBES, as evidenced by the fact that a large number of employer reporting errors were identified and brought to SSA's attention by the public in response to receipt of a PEBES. Early detection and correction of these errors helps SSA ensure accurate benefit payments when these wage earners become eligible for Social Security benefits.

Question. What is the status of SSA's plans to begin sending these PEBES statements to all covered workers whether they request them or not?

Answer. SSA's current plans are to meet the requirements of section 10308 of P.L. 101-239 (the Omnibus Budget Reconciliation Act of 1989). SSA now issues personalized earnings and benefit estimate statements (PEBES) to all workers upon request. By September 30, 1995 SSA will issue PEBES to all workers who attain age 60 by October 1, 1994 (and in fiscal years 1995 through 1999 for those attaining age 60 in those years), together with a notice that the statement is updated annually and available upon request. By October 1, 1999 SSA will issue PEBES to all workers age 25 and over, except that no estimate of future retirement benefits is required for workers under age 50.

REVIEW OF STATE DISABILITY DECISIONS

Question. The Social Security Administration is required to review at least 65 percent of favorable State disability decisions (commonly referred to as preeffectuation review (PER). SSA selects all review cases randomly. The Social Security Administration knows from its quality assurance data that some types of decisions are more difficult for the State agencies than others. Why don't you focus your sample on the more error-prone cases or decisions, rather than a random-selection approach?

Answer. The level of staffing required to perform the current legislatively-mandated 65 percent PER does not give SSA the flexibility to target reviews. We intend to target reviews if the Administration's current legislative proposal to review 50 percent of initial allowances is enacted.

Question. Wouldn't targeting the Social Security Administration sample under PER reviews result in greater savings than currently being obtained from SSA's random approach?

Answer. Yes, there would be more program savings with a 65 percent targeted sample as opposed to the current 65 percent random sample. SSA estimates that a 65 percent targeted sample would save an additional $8 million in program costs in FY 1991 as compared with a random sample. However, increased administrative costs would be necessary to achieve the program savings.

We believe that a better approach would allow us to select a targeted sample of allowances and continuances.

Question. Without expanding current resources could SSA begin targeting a portion of its PER reviews? If so, about what percentage of PER reviews could be targeted?

Answer. Yes SSA could target a portion of PER reviews but only if the mandated 65 percent PER level is reduced. If the 65 percent requirement is reduced to 50 percent of initial claims as contained in our pending legislative proposal, we could perform 50 percent targeted reviews without expanding current review resources.

Question. What additional resources (type and costs) would be needed if the Social Security Administration targeted its PER reviews at the mandated 65 percent review level?

Answer. To change from the existing 65 percent random review to a 65 percent targeted review would require a 30 percent increase in resources (about $5 million). These additional resources would include Federal disability case reviewers, medical consultants, and necessary support staff (supervisory and clerical). These resources would be necessary because targeted cases contain more difficult issues, which require more medical staff input; and they present more deficiencies, which take longer to review and to prepare detailed explanations for return of the cases to the State Disability Determination Services (DDS) for corrective action. In addition, these deficient cases require a second handling in the DDS (the corrective action) and in the review component to assure proper payment or denial.

MEDICAL CONSULTATIVE EXAMS

Question. Will the final regulations address the recommendations in GAO's December 1985 report, "SSA Consultative Medical Examination Process Improved; Some Problems Remain"?

Answer. The final regulations address the GAO recommendation of "Requiring States that use volume providers to establish standards for controlling consultative examinations (CE) appointment scheduling and/or examination duration." The final regulations also address indirectly most of the remaining GAO recommendations.

Question. Which recommendations, if any, will not be addressed, and why?

Answer. Those GAO recommendations which have not been expressly addressed in the regulations have been covered more appropriately through the development of additional and more detailed program operating guidelines, which will be issued after the final regulations are promulgated.

Question. Current regulations allow the States to determine the rates of payment for medical consultative examinations, so long as they not exceed the highest rate paid by any Federal or State agency within the State. Given these criteria, how do you assure that the State determined rates are reasonable?

Answer. The States are required to document the methodology used for establishing the rates of payment. SSA reviews the methodology and performs cost comparison studies (using other Federal agency fee schedules) to determine the reasonableness of the fees and the States' compliance with the regulations.

OUTREACH ACTIVITIES

Question. What steps are being taken to provide outreach, not just for potential SSA recipients, but those eligible for Food Stamps and Medicaid?

Answer. SSA is concerned about helping people obtain all the benefits for which they are eligible, and will, therefore, make appropriate referrals. However, SSA goes beyond that for both Food Stamps and Medicaid. For Food Stamps, SSA takes the following actions:

-- Asks SSI applicants if they are currently receiving food stamps and whether they want to apply;

-- If they want to apply, gives applicants who live in all-SSI households the option of applying for food stamps at the SSA office. (Applicants who do not live in all-SSI households or do not want to apply at the SSA office are referred to the Food Stamp office.);

-- Displays Food Stamp posters in its offices and makes Food Stamp pamphlets and application forms available; and

-- Obtains Food Stamp applications for individuals who are filing for SSI benefits while they are residents of public institutions because they will be released shortly.

For Medicaid, the connection with SSI is even closer. In 38 States and the District of Columbia, an SSI recipient will also be eligible for Medicaid because the eligibility requirements are generally the same. In 31 States and the District of Columbia, the SSI application is also an application for Medicaid, and field offices make the Medicaid eligibility determination along with the SSI determination. In the other States, SSA field offices refer SSI applicants to State Medicaid offices to file separate Medicaid applications. Since the SSI/Medicaid connection is so close, Medicaid eligibility is featured as an important benefit of SSI program participation in SSI public information materials.

Question. What efforts are being made to coordinate your outreach activities with those of the Agriculture Department under the Food Stamp program?

Answer. We have met with staff of the Food and Nutrition Service (FNS) to familiarize each other with the types of outreach efforts that are currently being pursued and that are planned. Our goal is to have the FNS join with us under a memorandum of understanding (MOU) which has already been executed among the Administration on Aging, the Health Care Financing Administration and SSA to promote the well-being of older persons. Under that MOU, the participating agencies will collaborate on activities that will increase program participation.

ADP PLANNING

Question. How can SSA assure itself that priority and resource levels for completing new initiatives, scheduling and acquiring resources, and implementing ADP projects are being effectively addressed when SSA is relying on an interim operational ADP plan, deemed deficient by its own consultant?

Answer. Full assurance can only come to SSA after the new Agency strategic plan is published and supporting plans are established. In the meantime, SSA has or is developing various processes and products to ensure that these aspects of systems management are effectively addressed. First, I have published goals and objectives for the Agency and specified which of these will have top priority over the next several years. These priorities are being used as the basis for high-level decisions about the activities that will be undertaken by the Agency. Systems projects which support such executive decisions are accorded the same priority consideration by the Systems Review Board, a board composed of SSA's top executives which reviews and prioritizes all Information Technology Systems (ITS) special expense item requests. A new process to ensure that the Agency's budget requests reflect its plans is being partially implemented this year. When it is institutionalized, the acquisition and scheduling of resources in all areas of the Agency will be facilitated.

Second, several systems-related plans, such as the target application software architecture and the capacity management plan, are now being used to guide short to mid-range systems development activities. Several new plans under development, such as the administrative information systems architecture and the application software/data development plan, will be used for such purposes as ensuring data base consistency and refining hardware and telecommunications requirements.

NATIONAL COMPUTER CENTER

Question. In April 1989 a Social Security Administration contractor stated that an alternate choice to continued increases in capacity at the Social Security Administration's National Computer Center (NCC) would be to off-load the mainframe cluster by transferring some of the expanding workload to additional machine capacity in the field. The contractor concluded that, at a minimum the Social Security Administration should conduct a systems analysis to determine the feasibility and cost/benefit ratio of deploying workload from the NCC to one or more field sites. Why hasn't the Social Security Administration explored this alternative for increases in capacity? What other efforts has the Social Security Administration made to increase computer capacity short of buying additional equipment?

Answer. We are in the process of designing a distributed processing pilot, in order to test the effects on the telecommunications network, the load on the mainframe systems and system security. We also will evaluate the cost and benefits for various applications.

However, distributed processing, by itself, does not lessen the Agency's capacity requirements. The capacity must exist either at the NCC or the distributed site. In fact, one of the costs of a distributed processing architecture is that it adds to the overhead costs of the system, which can in turn further increase capacity requirements.

Moreover, there are few real alternatives to meeting demonstrated capacity needs short of acquiring necessary equipment. SSA will be migrating to the Enterprise Systems Architecture as its mainframe operating software, which will reduce capacity requirements by about 10 percent. Whenever possible, SSA attempts to purchase needed equipment through government excess programs in order to minimize costs. Other than initiatives such as these, SSA must respond to genuine capacity needs by acquiring the equipment needed to meet them.

STATE DISABILITY DETERMINATION SERVICES

Question. Your FY 1991 budget states that the Administration's, "FY 1991 request fully funds the Disability Determination Services (DDS), State agencies which determine disability on behalf of SSA." Will "fully funded" DDS units, in FY 1991, be able to clear all remaining backlogs?

Answer. Initial claims pendings have risen in the past year. SSA's budget provides resources to reduce these backlogs.

Question. Will the DDS units be able to meet all statutory and regulatory requirements to process initial claims, to hear reconsiderations, and to administer the Continuing Disability Review process?

Answer. Priority is given in the FY 1991 budget to processing new claims and reconsideration cases in a timely fashion, including increased claims due to SSI outreach efforts.

CDR cases will be processed to the extent possible within the budget, and priority will be given to processing the medical improvement expected (MIE) cases. After a State completes its processing of the MIE cases, it will begin processing the medical improvement possible cases.

Question. Will the States be able to hire appropriate professional and support staff persons, in sufficient number, to fully administer the DDS program?

Answer. Yes, the FY 1991 budget assumes an appropriate mix of DDS staff in sufficient number to process expected workloads. In addition, there is a slight increase in productivity planned for FY 1991, the lowest planned increase in several years. We are seeking to improve staffing mix through a combination of automation initiatives and increased emphasis on recruitment in professional positions.

QUESTIONS SUBMITTED BY SENATOR PETE DOMENICI

800 NUMBER TELEPHONE SERVICE

Question. Commissioner King, you have indicated demand for the 800 number was multiples higher than SSA originally anticipated. Busy signals have been prevalent in the last few months. What do you consider an acceptable busy signal rate for your new 800 service?

Answer. We have recently established "bimodal" busy signal rate goals for the 800 number service. This dual goal approach was decided upon because calls to the 800 number - like all public contact with Social Security - is of a peaking nature. Workloads are higher to the 800 number service on "peak days" which are the days on and around the days when monthly payments are made, on Mondays and on days following holidays. The busy signal goal for these days is 20 percent. The goal for all other "regular" days is 5 percent.

Question. When, and how, do you anticipate reaching this acceptable busy signal rate?

Answer. It is our plan to reach the busy signal rate goals by the end of FY 1992. Analysis is currently underway to determine the steps and actions that are required to meet these goals.

Question. Do you plan to expand the 800 number teleservice centers to accommodate the much higher than expected call volume?

Answer. The 800 number service has been in operation nationwide less than 6 months. Any decision on expansion will be made after full analysis is completed. This analysis includes the potential use of additional backup units ("spike units") which could be used during peak calling periods. Currently there are two spike units in operation in Chicago and Birmingham. These units are made up of technical employees who regularly complete program service center work. Telephone and computer equipment have been provided so that these employees can answer calls at their current work stations for peak periods when backup is required.

DEPARTMENTWIDE FINANCIAL MANAGEMENT

Question. GAO has called for government-wide improvements in financial management systems. There are reportedly billions of dollars of differences between balances recorded in accounting systems and financial reports. What is your assessment of weaknesses in financial management of your agency?

Answer. The weaknesses in financial management in HHS can be directly attributed to the current antiquated financial systems in place. The systems are labor intensive in themselves, relying heavily on manual processing and report preparation. Also they are not properly linked to each other (e.g., procurement and core accounting). These deficiencies lead directly to the reconciliation problems reported by GAO.

Question. What specific areas could be strengthened, and what is your plan for making improvements?

Answer. Improvement of financial management systems is a major HHS initiative. The Department of Health and Human Services is implementing a project--the Phoenix Project--which is aimed at strengthening HHS financial management systems by:

- continuing to improve and standardize budget and financial information systems and processes for greater operating efficiencies and control,

- consolidating financial information into an agencywide perspective as required by OMB Circular A-127,
- implementing the U.S. Government Standard General Ledger in HHS,
- modernizing our automated financial management systems and those administrative management functions which provide data to Financial Management, and
- further improving compliance with OMB/GAO requirements and the Federal Managers' Financial Integrity Act (FMFIA).

The HHS plan addresses the need for the timely implementation of actions to address these priorities as they affect automated systems, both wholly within the Phoenix construct (e.g., the Operating Division (OPDIV) Accounting System), and for those which interface with it (e.g., the Personnel Payroll System).

The basic concept for the Phoenix Project derived from the Federal Government's reform '88 initiative which sought to reduce inefficiencies in governmental administrative and financial systems' operations, and to promote improved decisionmaking, accountability, and system integrity controls.

Question. Do your agree with GAO's assessment that managers need more and better training in Financial Integrity Act issues?

Answer. The Department agrees that training is a key element in implementing an effective FMFIA program. In this respect, the Chairman of the Council on Management Oversight has already requested the Assistant Secretary for Personnel Administration to develop a comprehensive departmentwide FMFIA training program. In addition, the Director, Departmental FMFIA Program, has been working with our office for Civil Rights and the Family Support Administration in a separate effort to train their staffs under the auspices of the Office of Personnel Management.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

SSI OUTREACH

Question. The FY 1990 appropriation for SSA included $3.5 million for outreach to potential recipients of Supplemental Security Income benefits. I am pleased that SSA has published a notice of its intent to establish priority areas for funding grants for SSI outreach. Please provide the subcommittee with a detailed description of plans to get these funds committed to outreach by the end of the fiscal year.

Answer. After receiving comments from the public in response to the Federal Register notice published on February 2, 1990, SSA plans to publish a formal announcement in the Federal Register in early April requesting applications for grants and cooperative agreements. Applications will be due by early June. Following an independent review, the applications will be scored and ranked. Successful applicants will be notified by September 30 of their selection and the amount of funding committed to each demonstration project.

Question. Has SSA established a cooperative agreement with the Administration on Aging to operate this outreach program?

Answer. SSA signed a memorandum of understanding (MOU) with the Administration on Aging and the Health Care Financing Administration to promote the well-being of older persons. The MOU provides that these agencies will collaborate on activities that will:

- Coordinate services funded under their respective services;
- Increase public awareness of those programs that promote the well-being of older persons;
- Increase program participation;
- Improve financial security and employment opportunities for the aged; and
- Improve health care for older people.

SSA is working closely with the Administration on Aging on SSI outreach. Because of the importance of the aging network to our outreach efforts, we have mailed copies of the February 2 Federal Register notice to each State and local area agency on aging. In addition, the Administration on Aging is supporting SSI outreach through its annual grant announcement published in the Federal Register on February 9, 1990.

SUBCOMMITTEE RECESS

Senator **Harkin**. Thank you very much. The subcommittee will stand in recess until 10 a.m., Friday, February 9. We will meet again here in SD–192.

[Whereupon, at 3:05 p.m., Wednesday, February 7, the subcommittee was recessed, to reconvene at 10 a.m., Friday, February 9.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1991

FRIDAY, FEBRUARY 9, 1990

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Bumpers, Reid, Adams, Specter, and Cochran.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

STATEMENT OF JAMES O. MASON, M.D., ASSISTANT SECRETARY FOR HEALTH

ACCOMPANIED BY:

- FREDERICK K. GOODWIN, M.D., ADMINISTRATOR, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
- ROBERT HARMON, M.D., ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION
- WALTER DOWDLE, M.D., ACTING DIRECTOR, CENTERS FOR DISEASE CONTROL
- J. JARRETT CLINTON, M.D., ACTING ADMINISTRATOR, AGENCY FOR HEALTH CARE POLICY AND RESEARCH
- JAMES R. ALLEN, M.D., M.P.H., DIRECTOR, NATIONAL AIDS PROGRAM OFFICE
- WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY FOR HEALTH OPERATIONS AND DIRECTOR, OFFICE OF MANAGEMENT
- J. MICHAEL McGINNIS, M.D., DEPUTY ASSISTANT SECRETARY FOR HEALTH (DISEASE PREVENTION AND HEALTH PROMOTION)
- W. HARELL LITTLE, DIRECTOR, DIVISION OF PHS BUDGET
- DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator HARKIN. Good morning. The Subcommittee on Labor, Health and Human Services, and Education, of the Appropriations Committee will come to order.

The hearing this morning will permit us to hear testimony first from Dr. James Mason concerning the fiscal year 1991 budget request for all the agencies included in the Public Health Service.

The fiscal year 1991 request for the several agencies within the jurisdiction of our subcommittee totals $14,991,157,000. Excluded from this total, but within the Public Health Service, are the budgets for the Food and Drug Administration and the Indian Health Service, which are under the jurisdiction of the Agriculture and Interior Subcommittees, respectively.

The committee is particularly pleased with the leadership that Dr. Mason has devoted to both the health objectives for 1990 and the newly released health objectives for the year 2000.

Collectively as a nation, we met only one-half of our health objectives for 1990. We partially met one-fourth and were uncertain with regard to the final fourth due to the lack of adequate data to evaluate our progress. Hopefully, we can do better in helping to meet the goals for the year 2000.

Because of my concern that we're not doing enough in the Nation to meet broad health prevention objectives, I introduced last week, along with a number of my colleagues, legislation to substantially increase the authorization for the principal health prevention vehicle, the prevention block grant within the Centers for Disease Control.

Another issue we would like to discuss with Dr. Mason this morning is the medical effectiveness research program, which is now included in the new Agency for Health Care Policy and Research. This morning the committee will receive a report from Dr. Mason on the progress to establish the new Agency.

Dr. Mason, we are pleased to have you with us this morning, and I leave the record open at this point for any opening statements which Senator Specter or other Senators might have.

I would also like to welcome Dr. Dowdle from the Centers for Disease Control, Dr. Goodwin from ADAMHA, Alcohol, Drug Abuse, and Mental Health Administration, and Dr. Harmon from HRSA.

What I propose that we do is, rather than questioning each individually, I would like to proceed in the following manner: hear testimony from Dr. Mason; then we will go to Dr. Dowdle, CDC, Dr. Goodwin, ADAMHA, and Dr. Harmon from HRSA.

That is not in any order of priority. That is just the way my book is arranged. [Laughter.]

PREPARED STATEMENT

So if we could do that, we will go on. And then after you have all had a chance to testify, then I think we will come back around for questioning. But I would like to get some idea of how these interrelate and everything, rather than just picking each person out specifically.

So again, Dr. Mason, welcome to the subcommittee. Your entire statement will be made a part of the record, and I would like to ask you to summarize or at least make the high points. I would ask of all of you, what are the three, four, five—I am not going to put any limit on it, but what are the things that you really think are important for us to really know here today?

Dr. Mason, welcome back.

[The statement follows:]

STATEMENT OF DR. JAMES O. MASON

I appreciate the opportunity to appear here today to discuss the FY 1991 budget request of $206 million for the Office of the Assistant Secretary for Health (OASH) appropriation and the Retirement Pay and Medical Benefits for Commissioned Officers request of $118.1 million.

The FY 1991 budget request includes $19.6 million for the Office of Minority Health; $4.6 million of this amount is for AIDS activities. This is an increase of $11.6 million over the FY 1990 appropriation, and includes $10 million for the Secretary's Minority Health Initiative to improve the health status of minorities. The Office of Minority Health was established in 1985 to implement the recommendations of the Task Force Report on Black and Minority Health. Some improvements in minority health status have been achieved. However, despite numerous efforts, there continue to be large disparities - in almost every category of mortality, death rates for minorities continue to be uniformly higher than for whites. Even more telling, life expectancy for Black American males is actually declining, and is now six years shorter than life expectancy for white males. We must not allow this trend to continue. The Office of Minority Health faces the great challenge of reversing this disparity and has assumed increasing responsibilities as the Department's advocate in issue areas which impact on the health of minority populations.

The Office of Minority Health acts as a catalyst to spur PHS and other public and private agencies to identify opportunities where existing programs and resources can be directed to promoting health and preventing disease among minority populations and to develop innovative strategies to improve the health status of minorities. The increase for FY 1991 will allow us to significantly expand these cooperative activities. In addition to this catalytic and coordinative role, the Office administers two grant programs which are based on the premise that health promotion and disease prevention efforts can be more effective by expanding the base of community awareness and involvement in disease risk reduction efforts. Through one grant program, we have funded 26 minority community coalition demonstration projects. The second grant program has supported 38 AIDS/HIV education/prevention projects for developing culturally sensitive health education materials and strategies for reducing the risk for acquiring and transmitting the HIV infection and AIDS.

The budget request presented to you today includes $9.4 million to support the Adolescent Family Life (AFL) program's demonstration and research program at the 1990 level. This is the only Federal program solely focused on the complex issues and problems of early adolescent sexuality, pregnancy and parenting. Engaging in sexual activity places teens at risk not only of pregnancy, but also of sexually transmitted diseases, some of which are incurable, may cause sterility or even death. Premature pregnancy among unmarried teens places both the teen mother and her baby at increased risk of adverse health as well as for poverty and economic dependency.

AFL prevention programs develop family-centered approaches to encourage teens to abstain from sexual activity, while AFL care programs provide comprehensive services to pregnant and parenting teens and their babies. Adoption counseling and information is provided by all care projects to help teens decide whether to parent their child or make adoption plans. Evaluations indicate that AFL care projects have a positive effect in improving birth outcomes and improving the educational and occupational prospects of teen mothers. Evaluations of AFL prevention projects show that these projects change teens' knowledge about the risks of premature sexual activity and improve their attitudes toward postponing sexual activity.

In FY 1991, $139.1 million is requested to support the Administration's proposal for a State administered family planning program authorized under Title X of the Public Health Service Act. This is the same level of support as that provided in FY 1990 for the family planning discretionary grant program. Under the Administration's proposal, all Title X funds would be awarded directly to States and territories. This would enable States to better integrate Title X funds with other programs to provide primary health care and to improve access to maternal and child health programs. This proposal would also offer States increased flexibility to meet local needs and establish policies which reflect local standards for the provision of family planning services.

Since its inception in FY 1988, the National Vaccine Program (NVP) has provided coordination of all PHS vaccine activities and has provided added impetus to activities aimed at developing and introducing safer, improved acellular pertussis vaccines. This has included sponsoring studies in the United States and abroad such as the large scale pertussis vaccine field trial carried out in Sweden. In FY 1991 the NVP will continue to place priority on development of pertussis vaccines as well as other activities leading to "optimal prevention of infectious diseases through immunization and optimal prevention against adverse reactions to vaccines". The FY 1991 request of $6.9 million is an increase of $1 million over the FY 1990 appropriation which provided $3 million for a pertussis vaccine field trial, and $1.5 million for basic and applied research on the development of new candidate vaccines. In FY 1991 the increase of $1.0 million for the NVP will support an expansion in basic and applied research and support additional staffing. In addition to this budget request, $7 million is requested in the PHS Agencies to address other high priority NVP activities, including $4.5 million for NIH to carry out an additional pertussis field trial, as well as additional basic and applied research on pertussis vaccines. The balance of $2.5 million will be used for monitoring vaccine safety, developing antibody tests and developing additional conjugated vaccines to prevent childhood meningitis.

The Office of Disease Prevention and Health Promotion's budget request of $4.5 million will provide Federal leadership for public and private action toward implementing the Year 2000 prevention goals and objectives; enable follow-up of the Surgeon General's Report on Nutrition and Health with key nutrition policy initiatives; strengthen the delivery of critical preventive services in medical practice and disseminate health information to the public.

The FY 1991 budget request includes $1.5 million to continue the program activities of the President's Council on Physical Fitness and Sports. This program consists of a variety of initiatives designed to promote knowledge and understanding about physical fitness, sports and health and to encourage participation in physical fitness activities. In FY 1991, emphasis will be placed on fitness for older adults, Native Americans, the protective services, the military, the family, and minorities, while continuing to promote physical fitness for all age groups.

The FY 1991 budget includes $3.9 million for the National AIDS Program Office. This Office is the PHS component responsible for coordinating all PHS efforts to prevent and control the occurrence and spread of AIDS and HIV infection. The Office serves as the primary staff support to the Assistant Secretary for Health for PHS policies and activities concerning HIV/AIDS activities and programs.

For the management and direction of the Public Health Service (PHS), we are requesting $21.1 million and 274 FTEs. This staff assists the Assistant Secretary for Health, in his role as line manager of the PHS, with the development of PHS policy and the coordination of a myriad of management functions. In FY 1989 through the efforts of the debt management staff, $79 million was collected and paid into the U.S. Treasury. The FY 1991 request provides resources to support the current level of management effort.

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

The Retirement Pay and Medical Benefits for Commissioned Officers appropriation provides retirement payments to Public Health Service Commissioned Officers, payments to survivors of officers who elected to receive a reduced annuity, and for the costs of medical care of active duty and retired officers, their dependents and survivors.

Mr. Chairman, I will be pleased to answer any question you may have.

Mr. Chairman, members of the committee, I am pleased to be here today to present President Bush's budget proposal for the Public Health Service (PHS) and to report briefly on some of our activities and plans.

For the PHS programs within this subcommittee's purview, the budget request totals $13.9 billion, an increase of $484 million over 1990. Much of what we are asking for today, I consider to be an investment in the future -- For those who are critically ill with AIDS, cancer, or other life threatening diseases, and can only hope that, through research, we discover a cure -- and for those people, especially pregnant women and children, who do not have adequate health care. Our children should not be born with debilitating conditions that could have been avoided by adequate prenatal care, and the United States should not rank 22nd in infant mortality. Our Nation's poor and underserved populations should not wonder from one day to the next whether a doctor will be there to heal them. And we need to help those people addicted to drugs, and to help prevent others from becoming addicted.

The 1991 increase of $484 million will enable us to stabilize and expand basic and biomedical research at the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); expand the Medical Treatment Effectiveness Program (MEDTEP); expand efforts to further suppress the national appetite for drugs through ADAMHA research, prevention, and treatment activities; continue the dramatic explosion of knowledge in HIV/AIDS research, treatment, and prevention; and improve access to health care for some of our most vulnerable underserved populations through the Secretary's Initiatives aimed at reducing infant mortality and improving minority health.

Investing in the Future - Research
An increase of $436 million is requested for the research and development programs of NIH and ADAMHA for a total of $8.9 billion. This request will enable us to support a total of 22,842 research project grants, the highest level in history and an increase of 184 over 1990. This includes AIDS and drug related programs. This level of support will provide for a continued emphasis on basic research as well as increases for infrastructure repairs at the NIH campus. This includes an increase of $48 million for the Human Genome Initiative, a long-term effort to map and sequence the entire complement of genetic material that determines human life. It is expected to dramatically improve our ability to treat more than 3,500 diseases of known genetic origin, and allow us to better understand many other diseases. New technologies discovered during the course of the initiative will also have applications in agriculture and environmental science. Also, ADAMHA will be able to address its major research initiatives including the implementation of the National Plan for Research on Schizophrenia and the Brain, and a formal program for the development of medications for the addictive and mental disorders.

The budget request includes $110 million (in obligations) for the Agency for Health Care Policy and Research, formerly known as the National Center for Health Services Research and the Health Care Technology Assessment. Spending for this new agency will include $49 million to expand the Medical Treatment Effectiveness program, an increase of $11 million over 1990. The Medical Treatment Effectiveness program is a comprehensive and a multi-agency effort to study the outcomes, effectiveness, and the appropriateness, of health care services and procedures, to find out what difference medical care makes with respect to outcomes. In addition, the Medical Treatment Effectiveness program will develop new data bases to answer this question, disseminate research findings, and support the development of practice guidelines.

Anti-Drug Abuse Activities
The Administration's commitment to reducing the demand for illegal drugs is emphasized in National Drug Control Strategy II and the ADAMHA budget request. Recent surveys reveal that the drug abusing population has diminished, however, the battle is far from being won. ADAMHA anti-drug abuse programs will spend $1.4 billion in FY 1991, a net increase of $179 million over FY 1990. This level will provide increases over FY 1990 in almost all aspects of our efforts to curb and prevent drug abuse. The request includes an

18 percent increase in Drug Abuse research, 21 percent increase for prevention, and 12 percent increase for treatment. The budget request includes an increase of $100 million for the drug portion of the in the ADMS Block Grant and $50 million in new funds for the Community Prevention Program, an effort similar to the Robert Wood Johnson Foundation's Matching Grant program.

Intensifying efforts to understand and prevent AIDS and HIV Infection

A net increase of $109 million ($101 million when you exclude FDA and IHS) is requested for AIDS activities supported through PHS, bringing the total support for research, prevention and other related activities in the war against AIDS and HIV infection to $1.7 billion in FY 1991. Over the past year, PHS has continued to make significant advances in its battle against HIV/AIDS. In the research area, preclinical screening and development capacity was expanded: Researchers discovered several different types of chemical structures which were shown to have anti-HIV activity potential; NIAID Trial Groups were expanded from 47 in 1989 to 57 in 1990; and 4 new drugs (ddC (dideoxycytidine), second generation soluble CD4-immunoglobulin, AZT with GM-CSF (granulocyte/macrophage colony stimulating factor), and soluble CD4) entered Phase 1 clinical trials. The new community program for clinical research on AIDS was initiated and awards were made to 18 (totaling $9 million) community-based research centers. Studies have shown that AZT can delay disease progression in HIV-infected persons at preclinical stages of HIV infection. Another study has shown that reduced dosage of AZT are effective and less toxic. A new drug dideoxyinosine (ddI) entered Phase II clinical trials and through an expanded availability system developed jointly by FDA and NIH, the drug is now available to be used by patients who cannot tolerate AZT. The NIH upgraded supercomputer will have the capacity to predict the structure of the HIV genome and work is underway to accomplish this. The Centers for Disease Control (CDC) has expanded its HIV/AIDS prevention efforts to inform and educate the American public with a special emphasis on high-risk and minority populations. In 1990, CDC supported 64 minority and community-based organizations in 27 metropolitan areas with high numbers of reported AIDS cases. Surveys indicate that the Nation's population has a good understanding of how HIV is transmitted and that the level of misinformation about HIV/AIDS is being reduced. Prevention efforts were also expanded through the testing, counseling, partner referral programs and perinatal prevention projects.

Improving Access to Health Care

This budget will further the PHS capacity to improve access to health care. As you know, many variables affect good health--genetics, lifestyle, nutrition, preventive care--to name a few. Key to all of these is access--access to information about what contributes to good health and access to qualified health care providers. Unfortunately, for some of our most vulnerable citizens, getting the service of qualified health professionals and learning about and assuming responsibility for ones' own health is difficult. This budget will take an important step toward improving the health of disadvantaged Americans, through addressing access to health care in two crucial problem areas: In the area of infant mortality, the United States continues to rank 22nd among all the nations. The problem is most dramatic for black infants, who continue to experience twice the risk of infant deaths and low birth weight as do whites--ratios that have remained unchanged over two decades. For black Americans, the 1987 mortality rate was 17.9 deaths per 1,000 live births. This request includes an increase of $63 million in PHS programs as part of an initiative for reducing infant mortality for underserved populations. This includes a new $25 million "one-stop-shopping" initiative to be carried out through the Maternal and Child Health program. This effort is designed to encourage the states to unite a variety of health and social services for pregnant mothers and infants, thereby making access simpler. Other PHS increases directed at reducing infant mortality include: case management services for low-income populations, community and migrant health center physician retention increases, and infant health epidemiology efforts to better define the parameters associated with adverse pregnancy outcomes. This initiative includes an increase of $12 million in the epidemic services activity to expand CDC's assistance to States in applying surveillance and epidemiological principles to identify community specific infant mortality risk factors and to expand maternal smoking cessation programs for high risk populations. Intervention strategies to reduce infant mortality rates will be tailored for local health jurisdictions based on the results of these surveillance findings. In keeping with the Administration's commitment to support the access to health care services for minority populations, the 1991 budget request includes an additional $117 million for a new initiative directed at increasing both the number of minority health professionals and sustaining the faculty at minority medical institutions. This initiative will support innovative community-based approaches to recruiting minorities into health service careers and creative new strategies to providing health care services for populations in HUD and other public housing projects.

I will be pleased to respond to any questions you may have.

BIOGRAPHY OF DR. JAMES O. MASON

James O. Mason, M.D., Dr. P.H., was sworn in April 21, 1989, as Assistant Secretary for Health, Department of Health and Human Services. Dr. Mason was nominated by President Bush April 7, 1989, and confirmed by the Senate April 19, 1989.

Before assuming responsibility for the U.S. Public Health Service, Dr. Mason had served, since 1983, as director of the Centers for Disease Control and administrator of the Agency for Toxic Substances and Disease Registry. During his tenure at CDC, Dr. Mason also served as acting Assistant Secretary for Health from February to December 1985. Dr. Mason served as executive director of the Utah Department of Health, with responsibility for health and health care financing, from 1979 to 1983. He was associate professor and chairman of the Division of Community Medicine, Department of Family and Community Medicine, at the University of Utah College of Medicine from 1978 to 1979. He directed a multiple-hospital health care corporation owned by The Church of Jesus Christ of Latterday Saints from 1970 to 1975.

As Assistant Secretary for Health, Dr. Mason directs the activities of the Public Health Service, which includes eight agencies: the Alcohol, Drug Abuse and Mental Health Administration; the Centers for Disease Control; the Agency for Toxic Substances and Disease Registry; the Food and Drug Administration; the Health Resources and Services Administration; the National Institutes of Health; the Indian Health Service; and the Agency for Health Care Policy and Research.

Dr. Mason provides policy guidance as well for HHS programs outside of PHS, and maintains relationships with other government and private agencies concerned with health. He advises and assists the Secretary on health policy and on all health-related activities of the department.

Dr. Mason was born June 19, 1930, in Salt Lake City, Utah. He received his B.A. and M.D. degrees from the University of Utah in 1954 and 1958. He received his master of public health and doctorate of public health from the Harvard School of Public Health in 1963 and 1967. Dr. Mason served his internship at Johns Hopkins Hospital in Baltimore from 1958 to 1959, and was an internal medicine resident at Peter Bent Brigham Hospital, Harvard Medical Service, in Boston from 1961 to 1962.

He has received numerous honors and awards. Among these are the Public Health Service Distinguished Service Medal (1988) and the University of Utah's Distinguished Alumni Award (1973). He is a member of a number of honorary and professional societies including the American Medical Association, the Institute of Medicine of the National Academy of Sciences, and the American Public Health Association. He has served on many national and international committees, councils, boards and task forces, including the United Nations Development Program/World Bank/World Health Organization Special Program for Research and Training in Tropical Diseases, Scientific and Technical Advisory Committee; and the National Institutes of Health Recombinant DNA Advisory Committee.

Dr. Mason is certified by the American Board of Preventive Medicine. He has written numerous articles and book chapters on a wide range of subjects related to the prevention and control of disease. He is a national spokesperson on the prevention and control of infectious disease, chronic disease and injury, and a leading architect of public policies concerning these health problems.

Dr. Mason and his wife, the former Marie Smith, have five sons and two daughters: James, Susan, Bruce, Ralph, Samuel, Sara and Benjamin.

STATEMENT OF DR. J. JARRETT CLINTON

I am pleased to appear before you today to discuss the Fiscal Year 1991 budget request for the Agency for Health Care Policy and Research.

The Agency for Health Care Policy and Research was established with enactment of the Omnibus Budget Reconciliation Act of 1989 (Public Law 101-239). The purpose of the Agency, as stated by law, is to enhance the quality, appropriateness, and effectiveness of health care services and access to such services through the establishment of a broad base of scientific research, through the promotion of improvements in clinical practice, and in the organization, financing, and delivery of health care services. The new Agency supercedes the National Center for Health Services Research and Health Care Technology Assessment, previously funded in the Office of the Assistant Secretary for Health.

The Agency for Health Care Policy and Research is the newest agency of the Public Health Service but it is built on a solid foundation. Over the last two decades, our predecessor, the National Center for Health Services Research and Health Care Technology Assessment, supported research that has directly supported the work of the Congress. For example, our research provided the foundation for:

- the Medicare DRG payment system and the Rural Health Clinics Act;
- severity of illness measures, which may be used to adjust DRG payments in the future;
- approaches for measuring and improving the quality of patient care;
- measures of disability and health status, such as the ADL (Activities of Daily Living) scale that Congress has used to target disability legislation;
- computerized medical information systems to monitor patients and assist health care providers in diagnosing and treating illness;
- the design of the nation's Emergency Medical Systems; and,
- enhancing the acceptance of the important role that nurse practitioners and physician assistants can play in patient care by supporting research that demonstrated both the quality and cost-effectiveness of the care that they can provide to patients.

The breadth and scope of these past research efforts has left the Agency for Health Care Policy and Research well-positioned to move quickly and aggressively in the new directions mandated by Congress in the Omnibus Budget Reconciliation Act of 1989.

The Fiscal Year (FY) 1991 budget request for the Agency for Health Care Policy and Research is $110,239,000 in total obligations.

This represents an increase of $11,401,000 or 11.5 percent over 1990 obligations. The Agency's 1991 budget request is comprised of the following sources of funds: an appropriation from the general funds of the Treasury of $39,126,000; transfer from the Medicare Trust Funds, pursuant to Section 1142(i) of the Social Security Act, of $28,000,000; reimbursement from the Medicare Trust Funds for health care technology assessment, $1,037,000; 40 percent of the maximum amount authorized for evaluations under section 2611 of the Public Health Service Act, pursuant to section 926(b) of said Act, estimated to be $40,776,000; and one-half of one percent available for National Research Service Awards, $1,300,000, pursuant to section 487(d)(3)(B) of the Public Health Service Act.

Medical Treatment Effectiveness:
The budget request includes $49 million for the Medical Treatment Effectiveness Program, an increase of $11 million or 29 percent over the FY 1990 level of $38 million. As stipulated in Section 1142(i) of the Social Security Act, two-thirds of the request, or $28 million, will be provided from the Medicare Trust Funds; one-third, or $14 million, will come from the general fund of the Treasury; and an additional $6.5 million from PHS 1% evaluation funds will be allocated for evaluative research under this program.

The Medical Treatment Effectiveness Program is a Presidential initiative to improve the effectiveness and appropriateness of health care services and procedures through a better understanding of the effects of health care practices on patient outcomes. The ultimate goal of the program is to provide information to patients and practitioners that will improve the health of our population and optimize utilization of scarce health care resources. This is a departmental program which involves formal collaboration with other agencies of the Public Health Service and the Health Care Financing Administration. Major components of the program are outcomes research and data development, guidelines development, and dissemination and assimilation of findings. Specifically, the program supports the development of scientific knowledge about patient outcomes through: the development of methodologies to support outcomes research; the development and supplementation of databases to support outcomes research; the support and conduct of outcomes research; the dissemination of information derived from outcomes research; and the development and periodic review and updating of clinically relevant guidelines, standards, performance measures, and review criteria. The increase in funds requested for this important Presidential initiative will continue the momentum given to the program in 1990 by providing substantial increases for all components of the program.

General Health Services Research and Health Care Technology Assessment:
The budget request for general health services research and health care technology assessment, including dissemination and program support is $51 million in 1991. This includes $14.6 million in budget authority and $1 million to be transferred from the Medicare Trust Funds. In addition, $34.3 million is estimated to be available for evaluations under this program and $1.3 million is estimated to be available for National Research Service Awards .

The $14.6 million in budget authority will continue to support approximately the 1990 level for research, and the dissemination of information deriving from research, on health care services and on the systems for the delivery of such services. Specific research includes such activities as health care services in rural areas, clinical practice, health care technologies, health care costs, productivity and market forces, primary care, long-term care, minorities and the disadvantaged, and medical liability.

As provided by section 926(b) of the Public Health Service Act $34.3 million is included for evaluative research in general health services and technology assessment in 1991. Of these funds, $20.5 million will support research on the delivery of health services to minorities and the disadvantaged, rural health research, primary care, health promotion and disease prevention, and medical liability. The other $13.8 million will continue support for the National Medical Expenditure Survey and the Hospital Studies Program.

The 1991 budget request includes transferring $1,037,000 from the Medicare Trust Funds, the same as 1990, for health care technology assessment activities.

Similar to 1990, the Agency for Health Care Policy and Research also will award an estimated $1.3 million for National Research Service Awards in 1991.

Acquired Immune Deficiency Syndrome/Human Immunodeficiency Virus: The budget request includes $10.5 million for health services research on AIDS and HIV related illnesses, an increase of $2 million over 1990. The Agency for Health Care Policy and Research will support research to study the availability, cost, and utilization of services for different HIV risk groups, populations, geographic areas, and stages of illness and treatment modalities. The increase of $2 million will expand the AIDS Cost and Service Utilization Survey to address the health resource utilization of the asymptomatic population.

Mr. Chairman and Members of the Committee, I will be pleased to answer any questions you may have on the specifics of this budget request.

BIOGRAPHY OF DR. J. JARRETT CLINTON

EXPERIENCE

Present	Acting Administrator, Agency for Health Care Policy and Research, Public Health Service, Rockville, Maryland
1988 - 1989	Director, Bureau of Health Professions Health Resources and Services Administration Public Health Service Rockville, Maryland
1984 - 1988	Deputy Assistant Secretary of Defense for Professional Affairs and Quality Assurance Office of the Assistant Secretary of Defense for Health Affairs Washington, D.C.
1983 - 1984	Associate Administrator for International Affairs, Alcohol, Drug Abuse, and Mental Health Administration Public Health Service Rockville, Maryland
1981 - 1982	Agency Director for Health and Population Agency for International Development Washington, D.C.
1978 - 1981	Senior Representative for South and East Asia The Population Council Bangkok, Thailand

1976 - 1977	Senior Consultant in International Health Family Health Care, Inc. Washington, D.C.
1969 - 1975	Population and Health Officer Agency for International Development USAID Mission to Indonesia Jakarta, Indonesia
1968 - 1969	Graduate Student, Department of International Health, Johns Hopkins School of Hygiene and Public Health
1966 - 1968	Deputy Director and Regional Medical Officer Office of Medical Programs Peace Corps Washington, D.C.
1965 - 1966	Peace Corps Physician Pakistan and India

EMPLOYMENT STATUS

Assistant Surgeon General, O-8
United States Public Health Service

EDUCATION

1983	Senior Fellows Program JFK School of Government Harvard University Cambridge, Massachusetts
1968 - 1969	MPH - Johns Hopkins University Baltimore, Maryland
1960 - 1964	MD - Kansas University Lawrence, Kansas
1956 - 1960	BA - Baker University Baldwin, Kansas

CERTIFICATION

Medical License, Virginia

Diplomate, American Board of Preventive Medicine (Public Health), 1973

MEMBERSHIP

American Public Health Association
Commissioned Officers Association
Association of Military Surgeons of the United States
Delta Omega, honorary public health society

AWARDS

1968	Foreign Duty Award, Public Health Service
1968	Isolated Hardship Award, Public Health Service
1975	William Jump Memorial Award for Public Administration
1982	Carl S. Schultz Award of the Population and Family Planning Section, American Public Health Association
1988	Secretary of Defense Award for Outstanding Public Service
1988	Meritorious Service Medal, Public Health Service
1988	Outstanding Service Medal, Public Health Service

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INTRODUCTION OF ASSOCIATES

Dr. MASON. Thank you very much, Mr. Chairman. We are delighted to have this opportunity to appear before you this morning.

I would like to mention that next to me is Mr. Harell Little, who helps me directly with the budget. Bill Forbush, hold up your hand—Deputy Assistant Secretary for Health; and Dennis Williams, who is Deputy Assistant Secretary for Health in the Office of Management and Budget in the Office of the Secretary.

Behind me are some other wonderful stalwarts that we will probably introduce later in the hearing.

For the Public Health Service programs within this subcommittee's purview, the budget request totals $13.9 billion, an increase of $484 million over 1990. Much of what we are asking for today I consider to be an investment in the future, for those who are critically ill with AIDS, cancer, or other life-threatening diseases and can only hope that through research we can discover a cure, and for those people, especially pregnant women and children, who do not have adequate health care.

Our children should not be born with debilitating conditions that could have been avoided by adequate prenatal care, and the United States should not rank 22d in infant mortality.

Our Nation's poor and underserved populations should not wonder from one day to the next whether a doctor will be there to heal them. We need to help those people addicted to drugs and to help prevent others from becoming addicted.

The 1991 requests for an increase of $484 million that will enable us to stabilize and expand basic and biomedical research at the National Institutes of Health [NIH] and the Alcohol, Drug Abuse, and Mental Health Administration [ADAMHA].

It will allow us to expand the Medical Treatment Effectiveness Program. And also allow us to expand efforts to further suppress the national appetite for drugs through ADAMHA research, prevention and treatment activities.

It will continue the dramatic explosion of knowledge in HIV-AIDS research, treatment, and prevention. It will improve access to health care for some of the most vulnerable and underserved population through the Secretary's initiatives aimed at reducing infant mortality and improving minority health.

An increase of $436 million is requested for the research and development programs of NIH and ADAMHA, for a total of $8.9 billion. This request will enable us to support a total of 22,842 research project grants, the highest level in history, an increase of 184 over 1990.

The budget request includes $110 million in obligations for the new Agency for Health Care Policy and Research, formerly known as the National Center for Health Services Research and Health Care Technology Assessment. Spending for this new agency will include $49 million to expand the Medical Treatment Effectiveness Program, an increase of $11 million over 1990.

The Medical Treatment Effectiveness Program is a comprehensive and a multiagency effort to study the outcomes, effectiveness, and the appropriateness of health care services and procedures, to find out what difference medical care makes with respect to outcomes.

In addition, the Medical Treatment Effectiveness Program will develop new data bases to answer this question, to disseminate research findings and to support the development of practice guidelines.

The administration's commitment to reducing the demand for illegal drugs is emphasized in National Drug Control Strategy No. 2 and the ADAMHA budget request. ADAMHA antidrug abuse programs will spend $1.4 billion in fiscal year 1991, a net increase of $179 million over 1990.

This level will provide increases in almost all aspects of our efforts to curb and prevent drug abuse. The request includes an 18-percent increase in drug abuse research, 21-percent increase for prevention, and 12-percent increase for treatment.

A net increase of $109 million, $101 million when you exclude Food and Drug Administration [FDA] and Indian Health Service [IHS], is requested for AIDS activities supported through the Public Health Service, bringing the total support for research, prevention, and other related activities in the war against AIDS and HIV infection to $1.7 billion in 1991.

This budget will further the PHS capacity to improve access to health care. As you know, many variables affect good health—genetics, lifestyle, nutrition, preventive care, to name a few. Key to all of these is access: access to information about what contributes to good health and access to qualified health care providers.

Unfortunately, for some of our most vulnerable citizens, getting the service of qualified health professionals and learning about and assuming responsibility for one's own health is difficult.

This budget will take an important step toward improving the health of disadvantaged Americans through addressing health access to two crucial problem areas. In the area of infant mortality, the United States continues to rank 22d among all nations. The problem is most dramatic for black infants, who continue to experience twice the risk of infant deaths and low birth weight as do whites.

This request includes an increase of $63 million in PHS programs as part of an initiative for reducing infant mortality for underserved populations. In keeping with the administration's commitment to support the access to health care services for minority populations, the 1991 budget request includes an additional $117 million for a new initiative directed at increasing both the number of minority health professionals and sustaining the faculty at minority medical institutions.

This initiative will support innovative community-based approaches to recruiting minorities into health service careers and creative new strategies to provide health care services for populations in Housing and Urban Development and other public housing projects.

Thank you very much for allowing me to summarize my testimony.

Senator HARKIN. Dr. Mason, thank you very much for a very good summary.

CENTERS FOR DISEASE CONTROL

STATEMENT OF WALTER DOWDLE

Now we'll hear from Dr. Dowdle of the Centers for Disease Control.

Dr. DOWDLE. Thank you, Mr. Chairman. I am pleased to present the President's 1991 budget request for the Centers for Disease Control.

One cannot pick up a paper or a magazine or turn on the television without being reminded of the public's increasing interest and awareness in health and in improving the quality of life. We hope that CDC has played some small part in this awareness.

Unfortunately, it does not apply to all members of our society. This morning's front page story in the Washington Post on black-white health differences is a good example of that problem.

Most injuries and illnesses that plague this Nation in these modern times do not have to happen. They can be prevented. Prevention of injuries and diseases and promotion of healthy lifestyles are the most effective steps that we can take to increase human productivity and decrease spiraling medical costs.

Our budget request for 1991 is based on the increasing conviction that we have just begun to take advantage of our prevention and health promotion opportunities. This nearly $1.2 billion prevention budget attempts to hold the line on costs, but it allows for increased cost of living and program increases in two high priority areas, in keeping with the Secretary's initiative, infant health and HIV infections of children.

I am pleased to be able to summarize this report. Thank you, sir.

Senator HARKIN. Dr. Dowdle, I just wanted to make sure before we get into questions that the increased budget request for CDC is $1.172 billion?

Dr. DOWDLE. Yes, sir; $1.172 billion. There is an increase of $81 million. The two initiatives were the $11.5 million initiative for infant health and the $66 million for AIDS.

Senator HARKIN. $66 million for AIDS?

Dr. DOWDLE. Yes, sir.

PREPARED STATEMENT

Senator HARKIN. Thank you very much, Dr. Dowdle. We will place your statement in the record at this point.

[The statement follows:]

STATEMENT OF WALTER REID DOWDLE

Mr. Chairman, it is a pleasure to be here today for CDC's first Appropriations hearing in the new decade. The 1990's promise to be an exciting time for public health, a time when we will march forward toward the elimination of many of the health problems of the past and a time when new technologies will help us build a healthier future for all Americans. As one of the architects of the forthcoming national health objectives for the year 2000, CDC is looking to the future. We know that we cannot be complacent about our accomplishments. Our energies in the 90's must be directed at seeking increasingly creative ways to not only prevent disease, early death, and injury, but to enhance health and quality of life. Our 1991 budget request has been developed to help focus us in this direction.

Public health faces serious challenges in the 1990's. Infant mortality remains a serious national concern, as the United States has fallen from 7th to 22nd among developed countries in its infant mortality rate over the last two decades. The problem of infant mortality is particularly acute for black infants, who continue to experience twice the risk of infant death and low birth weight than do white infants--ratios that have remained unchanged over two decades. A challenge of the 1990's will be to help those at risk to adopt healthy behaviors that can reduce and prevent the incidence of infant mortality.

Preventing the spread of the human immunodeficiency virus (HIV) also continues to be a high public health priority. While important discoveries have been made that may help prolong the lives of those infected with HIV, a cure or vaccine for the deadly virus is not yet within reach. As the 1990's begin, HIV prevention continues to be the only way of slowing the spread of HIV. CDC directly supports minority and other community-based organizations that represent populations disproportionately affected by AIDS. Last year we developed and disseminated two sets of guidelines on preventing human immunodeficiency virus infection in the workplace. We supported both teacher training programs and prevention and surveillance programs in virtually every state in the country. Since October 1987, our National AIDS Public Information Campaign has secured over $36 million in free public service television airtime.

There are other public health challenges ahead in the 1990's. For many infectious diseases, we have diagnostic tests, antimicrobial agents, including several new antiviral drugs, and vaccines, but in some cases, such as influenza, the organisms keep changing. In others, such as AIDS or Lyme disease, entirely new diseases emerge. To be prepared for the future, we must employ the latest technology to develop even better diagnostic tests and newer methods of detecting the microbial changes which will lead to improved vaccines and other prevention strategies, treatments, and more effective ways of getting prevention programs to people. With aggressive leadership on our part and the commitment of our public and private-sector partners, we project that by the year 2000 we can eliminate rubella and measles, reverse the trend in hepatitis B, Lyme disease, and foodborne disease, and move toward our national goal of tuberculosis elimination.

Heart disease, cancer, stroke, and diabetes are examples of health conditions that are preventable; yet we have not applied all that we know to reduce them, particularly among minority groups. Prevention of these chronic diseases or their complications can be achieved through smoking cessation, improved nutrition, better physical fitness, and early detection and treatment. Skeptics question our ability to help people adopt healthier behaviors. But major community-based research programs in this country and Europe have proven that community programs that combine media campaigns, counseling, screening, comprehensive school health programs, and environmental changes do lower risk of cardiovascular and other chronic diseases. The challenge for the 1990's is to work with States and communities to adapt these interventions to other chronic diseases and to the needs of blacks, Hispanics, Native Americans and low-income populations. If we apply what we already know, we will see major decreases in uncontrolled high blood pressure, high cholesterol, stroke, and breast and cervical cancer deaths by the Year 2000.

One of the hallmarks of the 1980's was the recognition that motor vehicle fatalities, homicide, suicide, and other types of injury are important priorities for the public health community, and that proven public health interventions can be used to reduce their terrible toll on our society. One in four U.S. residents sustains injuries each year. The total lifetime cost of injuries sustained in 1985 was $158 billion. Over the last 5 years, we have delineated many of the causes of injury, identified important risk factors such as alcohol use, and tested ways to prevent not only injuries but also the disability that results from them. Our task for the 1990's is to build the teams from public health, transportation, law enforcement, and other fields that are needed to achieve dramatic reductions in injuries and deaths due to falls, drownings, motor vehicles, homicides, and suicides.

Occupational injuries occur at twice the rate of injuries in the home, and farming is the second most dangerous occupation in the country, after transportation workers. The 9 million farm workers and family members in the United States bear a disproportionate share of injuries and disease. CDC is leading the development of a comprehensive national system to prevent farm-related injuries and diseases. In addition, CDC will sponsor a Surgeon General's conference to exchange information, build consensus, and maximize collaboration in this effort.

The Institute of Medicine report on The Future of Public Health makes it clear that these are just a few of the challenges facing public health during the next decade. This report, published last year, emphasizes the need to strengthen the ability of State and local health departments to cope with this broad and complex array of prevention issues. A strong and efficient network of public health agencies--Federal, State, and local, working with their private sector partners--is the foundation for effective prevention programs in the 1990's.

Developments in scientific technology and innovative applications for disease prevention, and of course, our own talented and dedicated workforce, make us very optimistic about CDC's ability to meet the challenges of the 1990's. Mr. Chairman, with your support for this budget request of $1,171,755,000, including $509.1 million for HIV control, we will continue to provide leadership to the challenges of preventing disease, injury, disability, and improving the quality of life for all Americans.

BIOGRAPHY OF WALTER REID DOWDLE

POSITION : Deputy Director, Centers for Disease Control

BIRTHPLACE AND DATE : Irvington, Alabama, Dec. 11, 1930

EDUCATION : B.S. University of Alabama, Bacteriology 1955
M.S. University of Alabama, Bacteriology 1957
Ph.D. University of Maryland, Microbiology 1960

EXPERIENCE :

Jan. 1989 Present	Acting Director, Centers for Disease Control
Sept. 1987-Present	Deputy Director, Centers for Disease Control
Nov. 1986-Sept. 1987	Deputy Director (AIDS), Centers for Disease Control
1981-1986	Director, Center for Infectious Diseases, CDC
1979-1983	Assistant Director for Science, CDC
1973-1979	Director, Virology Division, Bureau of Laboratories, CDC
1968-1979	World Health Organization (WHO) Collaborating Center for Influenza, Director; Honorary Fellow (WHO)
1972-1973	John Curtin School for Medical Research, the Australian National University, Canberra, A.C.T., Australia
1964-1973	Chief, Respiratory Virology Unit, Bureau of Laboratories, CDC
1960-1964	Supervisory Research Microbiologist, Respiratory Virology Unit, CDC
1957-1960	Research Assistant, University of Maryland

TEACHING APPOINTMENTS: Adjunct Associate Professor, Department of Parasitology and Laboratory Practice, University of North Carolina, Chapel Hill, 1985-present.

ASSOCIATION MEMBERSHIP : American Association for Advancement of Science

American Public Health Association

American Society for Microbiology

American Society for Virology

Fellow, American Academy of Microbiology 1974-present

Infectious Diseases Society of America

Research Society of America

HONORS : CDC Medal of Excellance 1978

Senior Executive Performance Award 1980

PHS Superior Service Award 1981

HHS Distinguished Service Award 1982

Presidential Executive Rank Award 1982

Federal Executive of the Year Award 1983

Presidential Executive Rank Award 1984

Congressional Excalibur Award 1985

Senior Executive Performance Award 1985

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

STATEMENT OF FREDERICK K. GOODWIN

Senator HARKIN. Dr. Goodwin with ADAMHA. Dr. Goodwin.

Dr. GOODWIN. I am pleased to be here. I would like to point out that the budget is outlined in the handouts that I think you have, that give the distributions by activity. We are proposing in ADAMHA a $2.8 billion request, which we think will permit us to address, in a balanced manner, the diverse missions for which ADAMHA is accountable. Our primary and defining mission is research on mental and addictive disorders, with very urgent responsibilities for prevention and for treatment improvement, particularly focused on drug abuse, and for accelerating the transfer of research base knowledge into front line clinical treatment.

We think that there is a real potential advantage in having these treatment improvement and prevention programs in an agency that has so strong a research base.

We also have an ongoing responsibility for the administration of the ADMS block grant, including some new accountability requirement that are built into it.

As Dr. Mason said, fully one-half of our budget is focused on drug abuse. We have seen, in this country, a gradual shift from drugs as a general problem of use to a problem of addiction; that is, general use going down, and the proportion of users who are addicted going up.

The complexity of this problem is daunting. The need for a sophisticated array of research and treatments, as well as translation of research into treatment, is really critical in this area.

Specifically, we intend to integrate the basic and clinical research on drug abuse with the state-of-the-art treatment approaches that will be managed through the Office for Treatment Improvement, a new component of ADAMHA.

There is considerable expansion of the block grant, as well as expansion of the categorical treatment programs in the budget proposal before you. We are particularly proud to have Dr. Beny Primm, one of the leading drug treatment experts in the world, join us as the Director of the new Office for Treatment Improvement.

The ability of OTI to bring leadership to this area is reflected not only in the persona of a Dr. Primm, but also in its placement in an agency which also contains NIDA and the Office for Substance Abuse Prevention that is so credibly led by Dr. Elaine Johnson.

We are proud of our capacity to bridge from research into the practice, both in the treatment area and in the prevention area. And that bridge is bidirectional, because the demonstration programs give feedback to the researchers about what is most important to study; and the research is able to give feedback to the treatment and prevention systems to try to improve those systems to the state of the art.

This is a complex process, but we think having these programs all within the same umbrella agency will help us do this.

The block grant is increased to $1.3 billion in our request, as indicated in one of the handouts, and it provides funds for prevention and treatment on mental illness, alcoholism, and drug abuse.

I might point out that what is increasingly becoming the rule rather than the exception is comorbidity, that is, the coexistence of drug abuse, alcoholism, and mental illness. And indeed, the most treatment-resistant groups of each of these areas have more than one problem.

We have to be aware of this clinical reality of dual diagnosis when we plan treatment services, earmarks, and so forth.

The set-aside in the ADMS block grant is extremely important to us. We have only had this set-aside for a little more than a year, and it gives us the capacity to collect data that can provide valuable information about these programs. We have been without such information through the whole decade of the eighties.

These set-aside funds also allow us to provide technical assistance to help translate some of the research into practice, and to do a small amount of actual service system research, which fills the gap between university research and the world of clinical practice.

ADAMHA also intends to request treatment plans from the States although we do not have the full congressional authority for the treatment plans yet. This should help to provide availability from the States.

Our budget for research, which has been the constant thread of the ADAMHA mission, is nearly $1 billion, and this includes $230 million for our very important basic and behavioral research on AIDS.

We actually want to express deep appreciation to Congress for your support of ADAMHA research over the past 8 years. That support has helped us close a gap between ADAMHA's funding levels and those of the general health research community that had developed in the seventies. Today ADAMHA is really in a position to take advantage of considerable advances in the basic brain sciences and behavioral sciences as they apply to the problems of mental illness, drug addiction, and alcoholism.

Our priority is to pick research projects that have the highest likelihood of long-term payoff and to support emerging areas, such as those elucidated in the NIMH Decade of the Brain and NIMH's new national plan for research on schizophrenia. Also a priority is our focus on childhood disorders. In relation to what Dr. Dowdle said about prevention, we have seen, that identifying and treating childhood mental disorders very early can have, an impact on subsequent adolescent drug and alcohol abuse. Existing data that treatment of childhood mental disorder can help in that arena.

Genetic studies continue to be very important. We are taking advantage of new advances to understand the genetics of severe substance abuse, particularly alcoholism. We also are proposing specific treatment-matching research in alcoholism. For far too long, the treatment system in alcoholism and drug abuse has been based on "seat of the pants" assumptions and professional impressions of what is right, rather than controlled research. We really have to expand our knowledge base as we expand our treatment system.

A high priority in NIDA is the expansion of a medication development program. The ability to treat addiction requires an approach to the chemical trap of addiction, as well as to the psychosocial traps of addiction. One cannot hope for the psychosocial approaches to work unless we can find some way chemically, with a medication, to dampen the craving that drives so many people out of the good treatment programs.

PREPARED STATEMENT

We will support treatment research demonstrations that will expand treatment and expand knowledge at the same time. With the treatment research demonstrations, we are indeed making optimal use of our resources.

I am pleased to have a chance to summarize this and, later on, hope to be able to answer some questions.

[The statement follows:]

STATEMENT OF DR. FREDERICK K. GOODWIN

I am pleased to appear before you to discuss the President's fiscal year 1991 budget request for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

The request totals $2.8 billion, of which $1.3 billion is distributed directly to the States through block grants. Another $1.5 billion is requested to support research, treatment, and prevention activities focused on mental illness, alcoholism, and drug abuse; this amount includes $50 million for new grants in the "Community Partnership" drug abuse prevention program; $7 million for continuation of a rural mental health research initiative begun in 1990; and $72 million for programs targeted on the needs of homeless persons who suffer mental and addictive disorders. There is $1.4 billion in this budget for drug abuse, a 15 percent increase over last year. Also, the request includes $230 for ADAMHA's AIDS programs.

This budget will further our capacity, and that of the States and communities, to respond decisively and effectively to the evolving patterns and consequences of substance abuse in this country. Our request also anticipates the remarkable opportunities open to us to improve treatments for mental and addictive disorders on the basis of scientific findings regarding the fundamental biological and behavioral mechanisms involved in disorders which are estimated to cost the Nation $50 billion annually for clinical treatment and support services, and more than four times that amount in indirect costs associated with premature mortality, reduced productivity, crime, and social welfare programs.

We are pleased to report that our most recent data document a dramatic, continuing decline in the use of illegal drugs by the population-at-large. At the same time, we are very concerned by a parallel trend toward the increasingly pathological, addictive use of substances including crack, potent new designer drugs, and the combined use of alcohol and other drugs by a smaller number of users, with consequences that constitute a national tragedy.

While the destructive use of drugs is not limited to any subgroup of Americans, the severity of consequences is not distributed evenly. The toll of drug use among young male members of the Nation's urban underclass is unconscionable; the impact on the unborn children and infants of women of child-bearing age--and, specifically, the recent phenomenon of "crack babies"--is heartbreaking; the effects of drugs on the one-in-six persons who are mentally ill at any given time, or homeless, or who carry HIV, the AIDS virus, confound the already precarious situations of these specially vulnerable individuals.

The broad shift toward more dangerous patterns of drug use challenge us, as a Nation, to recognize that developing more effective treatments and strategies for preventing addiction requires a substantial and sustained research effort--and to realize that an integral part of that effort must entail a high priority on translating knowledge generated through research into improved treatment and prevention services.

A key element of ADAMHA's response to this challenge is an intensified commitment to our primary scientific mission--to generate new knowledge and to translate that knowledge into clinical practice. To that point, I would express appreciation to the members of Congress for your support, particularly over the past 7 to 8 years, of our research programs. Although the depth and quality of the knowledge base among and within the fields of mental illness, alcoholism, and drug abuse remains uneven, we are finding that advances in one field increasingly often inform the hypotheses and speed the pace of work in other fields. And, as sophisticated epidemiological research defines the frequency of comorbidity, or co-occurrence, of mental and addictive disorders, practical applications of such cross-fertilization of the knowledge base are more apparent.

Recently, we created an Office for Treatment Improvement in the Office of the Administrator to advance ADAMHA's ongoing national leadership initiatives to translate our knowledge base into improved treatment services. We are fortunate to have recruited Dr. Beny Primm, who is among the Nation's pre-eminent authorities on drug abuse treatment, to head the new OTI.

Under Dr. Primm's guidance, OTI extends to the clinical treatment arena the quality of dedicated expertise which ADAMHA currently possesses in the primary prevention sphere, embodied in the Office for Substance Abuse Prevention (OSAP). The OTI, I should note, also administers funds passed through ADAMHA in the form of the ADMS Block Grant and the Mental Health Services to the Homeless Block Grant, and monitors State accountability to its provisions.

The OTI and OSAP bridge the traditional research sector with the front lines of substance abuse treatment and prevention services, primarily through the application of new knowledge in the form of demonstration projects which apply research-based findings in large populations and which nourish research by identifying promising interventions which need further testing and refinement.

Because ADAMHA's research institutes--the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism--also support demonstration projects, let me anticipate questions that may arise regarding the division of responsibility between these two components of the Agency.

The demonstrations conducted by OSAP and OTI are designed to try out new approaches or methods that are based on state-of-the-science knowledge and theories. If one views our strategy as a "crash program," these projects represent our effort to test, immediately and in real-world settings, the feasibility of new prevention and treatment service models. The evaluation built into each project is intended to answer the specific question of whether a given approach "works" here and now.

Demonstrations conducted by the Institutes, on the other hand, are intrinsically of a research nature. That is, while these projects also are designed to translate "laboratory knowledge" into clinical uses, they involve rigorously matched controls for experimental variables in the new approach. Another key difference is that while OTI and OSAP demonstrations assess for project-specific effectiveness, the Institute's evaluations are designed to determine methodically if an approach that works in one setting can be applied with equal success to other settings and other populations.

Both demonstration approaches expand our treatment and prevention capacity while they are expanding and enriching our knowledge base. An example is seen in the District of Columbia initiative, under which NIDA will conduct research, in specially funded treatment clinics, designed to develop and demonstrate new model programs effective in treating drug abuse and establish appropriate combinations of treatment methods and approaches.

I should emphasize again that I am describing a two-way bridge, wherein research both informs and is informed by community experiences.

I also want to emphasize our commitment to basic and clinical research which will benefit all persons who suffer alcoholism, drug abuse, and mental illness. As you are aware, President Bush last July signed into law the congressional resolution declaring January 1990 to mark the advent of the "Decade of the Brain." His proclamation recognizes the enormous potential of the brain sciences to advance our understanding of some of the most serious disorders threatening the physical and mental health of the Nation--schizophrenia, major depression, Alzheimer's disease, childhood disorders, and alcoholism and other drug disorders.

Two new NIMH research strategies--the National Plan for Research on Schizophrenia and the Brain, and the National Plan for Research on Child and Adolescent Mental Disorders will serve as mileposts for our progress throughout this decade. Under the first of these initiatives, NIMH-funded studies recently have provided new insights into the basic genetic control and regulation of dopamine, a chemical messenger in the brain that is excessively active in schizophrenia.

In ongoing work at the NIAAA, computerized tomography is being used to characterize the actual physical changes that occur in brains of alcoholics. CT scans of age-matched alcoholic subjects and nonalcoholic controls reveal substantial, atypical-for-age damage in the brains of alcoholics, suggesting special susceptibility of the cortex to neurotoxic effects of alcohol. Thus, imaging technologies may be useful in the early diagnosis of alcoholism, and may lend themselves to the development of new treatment approaches for alcoholism.

As our understanding of the biological bases and sequelae of drug addiction has deepened, the identification, development, and large-scale clinical trials of medications designed to act specifically on brain neurochemical systems that are linked to tolerance and craving for drugs has emerged as NIDA's number one priority. Crack cocaine is one of the most addictive substances yet known and, because of an uncontrollable craving for cocaine, abusers tend to strongly resist available treatments. Recent results of a NIDA-funded study indicate that the medication flupenthixol offers singular promise in treating crack dependence. Outpatients receiving this medication experienced a rapid, marked reduction in cocaine craving and use, as well as a lessening of cocaine withdrawal symptoms. We hope to replicate these encouraging preliminary findings in a larger, double-blind, placebo-controlled study now being developed.

Finally, our budget request includes $12 million for the final subsidy payment for Saint Elizabeths Hospital. This subsidy is to assist the District of Columbia in assuming full operational responsibility for the hospital as authorized by Public Law 98-621.

I will be pleased to answer any questions you may have.

BIOGRAPHY OF FREDERICK K. GOODWIN

Frederick K. Goodwin, M.D., is Administrator of the Alcohol, Drug Abuse, and Mental Health Administration of the Department of Health and Human Services. ADAMHA is comprised of three research institutes--the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health--and two offices charged with public health applications of research--the Office for Substance Abuse Prevention and the Office for Treatment Improvement. As Administrator, Dr. Goodwin directs federal efforts to contribute scientific solutions to the public health problems associated with mental illness, alcoholism, and drug abuse. He was appointed by President Reagan, confirmed by the U.S. Senate, and subsequently reappointed by President Bush. He is the first federal scientist to have risen through the ranks to attain this high post.

A physician-scientist specializing in psychiatry and psychopharmacology, Dr. Goodwin served previously as Scientific Director of the National Institute of Mental Health (NIMH) and Director of NIMH's Intramural Research Program, the largest mental health and neuroscience research and research training program in the world. He joined the NIMH in 1965.

Dr. Goodwin is an internationally recognized authority in the research and treatment of major depression and manic depressive illness. He was first to report the antidepressant effects of lithium in a controlled study, and was a leader in the development of safe, effective techniques utilizing cerebrospinal fluid to measure changes in brain chemistry. Although he has made seminal scientific contributions in diverse areas, his research is characterized by key constants: attentiveness to the interaction of biological and psychological factors in mental illness; a focus on longitudinal observation of patients' experiences over the course of illness; and a commitment to scholarship.

A graduate of Georgetown University, Dr. Goodwin received his M.D. from the St. Louis University, and completed his psychiatric residency at the University of North Carolina in Chapel Hill. Among his many professional affiliations, he is a Member of the Institute of Medicine of the National Academy of Sciences. He serves on the editorial boards of key scientific journals, including the Archives of General Psychiatry, and is founder and co-editor-in-chief of Psychiatry Research.

Dr. Goodwin is a recipient of the major research awards in his field: the Hofheimer Prize from the American Psychiatric Association, the A.E. Bennett Award from the Society of Biological Psychiatry, the Taylor Manor Award, the International Anna-Monika Prize for Research in Depression, and the Edward A. Strecker Award. In 1986, President Reagan conferred upon Dr. Goodwin the highest honor available to a member of the career Federal service: The Presidential Distinguished Executive Award. In 1989 he was the first recipient of a new award: Psychiatrist of the Year (Best Teacher in Psychiatry) from the Psychiatric Times.

The author of more than 375 publications, Dr. Goodwin now has in press, with Oxford University Press, a comprehensive textbook on manic-depressive illness, co-authored with Dr. Kay R. Jamison. He is one of five psychiatrists on the Current Contents' list of the most frequently cited scientists in the world, and one of 12 psychiatrists listed in the Best Doctors in the U.S.

He is married to Rosemary Goodwin, a clinical social worker with expertise in alcohol and drug abuse treatment. They have three children.

Senator HARKIN. Dr. Goodwin, thank you very much. I will have some questions about that. I remember you were in my office and we talked about this some time ago.

We will see what progress has been made on those drugs. I know FDA has got some. They are under clearance process right now.

Dr. GOODWIN. Yes; we are getting good cooperation from FDA and they are treating the drug abuse area more like they have been treating the AIDS area in terms of acceleration.

Senator HARKIN. We discussed that.

Dr. Harmon, the new Director of HRSA, welcome.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

STATEMENT OF ROBERT HARMON

Dr. **HARMON**. Thank you, Mr. Chairman. This is my second week on the job and as I left Missouri, where I was the State Health Director, I received a number of plaques and so forth. I told my colleagues: These plaques are fine; what I would really like is a house in Bethesda. [Laughter.]

I do bring the State and local perspective. I also was a local health officer in Arizona previously, and I will be working closely with Dr. Mason and Dr. Sullivan to improve the working relationship of the Federal Government with the States and the localities.

The 1991 budget for HRSA continues the agency's preeminent role in providing health care and education to the underserved, the disadvantaged, and minorities. This budget of $1.6 billion will meet our commitments through community and migrant health centers, maternal and child health block grant, treatment programs for persons with black lung, Hansen's disease, AIDS, and other conditions, support for health professions students and institutions, and a wide variety of other activities dealing with organ transplantation, vaccine injury compensation, health care services for the homeless, and the initiative to reduce infant mortality.

I would like to direct your attention briefly to several new or expanded activities that we will be undertaking. We are seeking $107 million for the new minority health initiative, which includes expanded and revitalized programs on loan repayments and scholarships for service in underserved areas, a program to provide a full range of health care and social services in our public housing units, community-based recruitment of minorities and disadvantaged into health professions careers, and institutional support and faculty development to sustain minority enrollment levels at health professions schools.

We are proposing $25 million as an increase in the MCH block grant for the one-stop shopping approach to provide health care, financial assistance, social services, and other community support to pregnant women and to children. We are also expanding the infant mortality prevention project in community health centers, at $4 million. We will continue HRSA's strong involvement in fighting the AIDS epidemic through grants in areas with a high incidence of AIDS, pediatric service demonstration projects, education and training centers to instruct health care providers in better AIDS treatment, grants to community and migrant health centers for treatment of HIV-infected persons, and renovation grants for facilities to deliver better intermediate and long-term care.

PREPARED STATEMENT

We will focus our health professions support on programs designed to assist the minority and disadvantaged students as a top priority. In 1991 HRSA will address many opportunities and numerous challenges. I believe the budget we are presenting to you will enable us to take advantage and meet those challenges.

Thank you.

[The statement follows:]

STATEMENT OF DR. ROBERT HARMON

I am pleased to appear before you today to discuss the fiscal year 1991 budget request for the Health Resources and Services Administration (HRSA).

HRSA's clients are:

- mothers and children,
- the homeless,
- the poor and disadvantaged,
- minorities,
- the medically underserved,
- migrant workers,
- health professions students,
- persons with AIDS, chronic lung disease and Hansen's disease,
- those in need of organ transplants,
- those who are too sick to leave their homes.

HRSA programs span a wide range of activities. They:

- provide grants or support for personal health services to numerous special populations,
- aid in improving the education, supply, distribution, and quality of the Nation's health professionals; and
- provide technical assistance to enhance the utilization of the nation's health resources and facilities to support these efforts.

In fiscal year 1991, we are requesting approximately $1.6 billion and 1,528 full-time-equivalent positions. Our partners in this effort are State and local health departments, universities, private non-profit organizations, and many other participants in our nation's public health system.

Since 1982, when the HRSA was formed, its mission has continued to rapidly adapt to a changing environment. While our agency's essential focus has remained ensuring health services to persons who might not otherwise receive care, the agency has developed new and innovative approaches to providing that care. At the same time HRSA has accepted responsibility for new programs addressing current public health needs.

Community Health Centers

The FY 1991 request includes $438 million to continue support of approximately 550 grantees providing primary health care services to over 5 million medically underserved people. These underserved individuals include those without access to care because they lack insurance, live in communities without sufficient health resources, have health concerns not met by traditional medical care, or face other barriers to care. The request also includes funding to improve compensation packages for center physicians.

Migrant Health Centers

The FY 1991 request for Migrant Health Centers includes $48 million for the continued support of services to migrant and seasonal farmworkers and their families. Access to health care for this group is very difficult to achieve because of the lifestyle, language, culture, and economic status of most migrant and seasonal farmworkers. Services to approximately 500,000 individuals will be supported. The request also includes funds for improving the compensation for center physicians.

Infant Mortality

In 1991 we are expanding the Infant Mortality Prevention Initiative to $36 million, an increase of $4 million above the 1990 appropriation. This request will support an additional 22 community and migrant health centers to provide case managed services to 75,000 high-risk pregnant women. It also will expand overall perinatal capacity in community and migrant health centers to approximately 190,000 pregnant women per year. This will be accomplished through a proven case-managed, comprehensive approach that will focus on the coordination of appropriate services throughout the high risk mother's child bearing years.

Minority Health Initiative

The FY 1991 budget includes $107 million to launch a Minority Health Initiative. This initiative is made up of several programs designed to increase the number of minority health professionals and to reduce the health disparities between minority populations and non-minority populations as outlined in the 1986 Report of the Secretary's Task Force on Black and Minority Health.

These programs are designed to increase the number of health practitioners serving minority/disadvantaged populations. Key components include:

- the revitalized NHSC loan repayment/scholarship program ($55 million), which focuses support for loan repayments and special scholarships to financially disadvantaged students to serve in the community with which they are familiar,
- a new program, Health Services in underserved neighborhoods ($35 million), will provide a full range of health services in association with public housing units.
- The Health Professions Institutional Development program ($12 million), providing funds for faculty development and general institutional support to maintain minority enrollment levels,
  and
- Community Based Recruitment ($5 million), to support innovative efforts to recruit minority health professionals.

Maternal and Child Health

The Maternal and Child Health block grant allocates funds to States to provide a wide range of health services to mothers and children, including preventive and primary care and rehabilitative services which help alleviate infant mortality problems and provide better access to health care. Our 1991 request is for $579 million, an increase of $25 million above the 1990 current estimate. The request includes:

- $471 million for State Block grants,
- $83 million for special projects of regional and national significance (SPRANS) in the categories of research, training, hemophilia, genetic diseases, and maternal and child health improvement, and
- $25 million for One-Stop shopping to improve the delivery of health care services for pregnant women and infants.

National Health Service Corps

The National Health Service Corps program is designed to improve the capacity to provide health services in Health Manpower Shortage Areas (HMSA) and improve access to health care in these areas through the placement and support of health professionals. This program, and the related recruitment effort play a critical role in the attempt to reduce physician shortages in the most difficult to staff areas throughout the country. The budget request of $42 million will continue the program at approximately the 1990 level.

National Health Service Corps Recruitment

The budget request for NHSC recruitment is $64 million to support scholarships and loan repayments to health professionals and health professions students in exchange for service in a HMSA. The request includes an increase of $55 million associated with the Minority Health Initiative to support scholarships and loan repayments for disadvantaged and minority students.

Homeless

The 1991 budget provides $34 million in new budget authority for a total program level of $46 million for health care to the homeless. This request will support a broad range of primary care, alcohol and substance abuse, and mental health services to approximately 335,000 homeless individuals in approximately 92 health care for the homeless programs. Emphasis will be placed on providing preventive as well as curative services to a broad sector of the homeless including runaway adolescents, homeless pregnant women and children, and individuals with chronic substance abuse and mental health problems. Grants will be made to applicants demonstrating broad community participation and linkages with other community providers of critical support needs of the homeless and effective and efficient provision of care.

Health Professions

At the end of fiscal year 1990 the cumulative Federal investment in Health Professions will total nearly $9 billion. This investment has increased the supply of health professionals. Also, beginning in the late 1970's and through the 1980's, it has addressed more targeted objectives such as primary care, disadvantaged assistance, and improvement in advanced and specialized nurse training.

In recognition of these successes in programs the Administration proposes to shift the emphasis from health professions training to other targeted HRSA priorities such as reducing infant mortality, increasing the number of minority health professionals, providing health services to underserved populations, and supporting AIDS HIV programs.

HRSA will continue to administer the health professions and nursing revolving loan funds which will make available approximately $86 million for loans to about 32,500 students. The budget also includes $185 million in loan guarantee authority for the HEAL program to begin a phase-down.

In addition, the FY 1991 request continues funding for Exceptional Financial Need scholarships, Excellence in Minority Health, and the Disadvantaged Assistance programs which were included in President Bush's amended budget.

National Practitioner Data Bank

The President's FY 1991 Budget proposes to enhance the collection of user fees to cover the full cost of operations of the National Practitioner Data Bank. User fees collected in 1991 will fund the remaining cost of the first phase of the contract and to begin to implement Section V of P.L. 100-93, which will add other health professions to the databank. A primary objective for FY 1991 is to develop a system to monitor and assess compliance with the reporting requirements of the law and to report instances of noncompliance to the Secretary and to the Office of the Inspector General for field investigations.

Organ Transplantation

We believe that the allocation of organs for transplantation is more fair and equitable since the establishment of the national Organ Procurement and Transplantation Network. For example, the number of organs procured but not transplanted has decreased markedly. Also, fewer organs are being shipped overseas and, as a result, more U.S. residents, nation-wide, are receiving transplants. The 1991 budget request includes $3 million to continue support of the Network as well as the Scientific Registry used to track the scientific and clinical status of organ recipients. In additions, the request includes funds to continue support of the agency's Organ Transplantation staff.

Rural Health

The budget request includes $4 million for the Office of Rural Health Policy to fund a total of seven Rural Health Policy/Research Centers. These centers will provide an information base and a policy research capability on a wide range of rural health concerns including access to care, financing systems, alternative delivery systems, and occupational health issues. The request provides funding for a national rural health information center and to staff the National Advisory Committee on Rural Health. Funding to provide technical assistance for hospitals in fiscal trouble is also included.

AIDS

HRSA AIDS/HIV activities continue to be an important part of the battle to control this dreaded disease. In 1991, HRSA is asking for a total of $73 million for AIDS projects. The funds will be used as follows:

- $19.4 million to continue 7-11 of the HIV health service grants in communities with a high incidence of AIDS;
- $14.8 million to carry on the pediatric service demonstration projects started in 1988;
- $21 million to expand the Education and Training Centers set up to instruct health care and related providers in the care, treatment, and support of AIDS sufferers; continued emphasis for curriculum development on AIDS in our nation's health professions and nurse training institutions;
- $13.3 million to continue the program to provide care in community health centers for persons with AIDS/HIV infection, with the goal of helping to relieve the increasing burden on inpatient and long term care public facilities while improving efforts to mainstream the care for this population into the general health care system; and
- $4.1 for AIDS facilities renovation grants to support construction/renovation projects in nonacute intermediate and long-term care facilities.

Vaccine Injury Compensation Program

The National Childhood Vaccine Injury Act of 1986 established a program to provide compensation for vaccine-related injury or death. HRSA maintains the fiscal records of the claims trust fund and provides medical advice to the court. The 1991 HRSA budget estimates obligations of $222 million for claim payments and other costs to be disbursed from the Vaccine Compensation Trust Fund.

Conclusion

In conclusion I can assure the members that we at HRSA see the coming year as one with many opportunities and numerous challenges, and we are looking forward to working with you in moving the public health agenda forward.

Mr. Chairman and members of the Committee, my associates and I will be pleased to address any questions you may have on the specifics of this budget request.

BIOGRAPHY OF DR. ROBERT HARMON

Present Position:	Administrator and Assistant Surgeon General Health Resources and Services Administration U.S. Public Health Service Department of Health and Human Services
Previous Positions:	Director, Missouri Dept. of Health, Jefferson City, MO. January 1986-January 1990. Clinical Professor, Dept. of Family and Community Medicine. University of Missouri/Columbia School of Medicine. July 1986-January 1990.
Birthplace and Date:	Barnsdall, Oklahoma, March 20, 1944
Education:	B.A. - 1962-66, Washington University, St. Louis, MO M.D. - 1966-70, Washington University School of Medicine, St. Louis, MO M.P.H. - 1975-77, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, MD

Post Graduate Training:	Internship and residency internal medicine, University of Colorado Medical Center, Denver, CO. 1970-73. Certificate, Program for Senior Executives in State and Local Government, Harvard University, John F. Kennedy School of Government. July, 1988.
Professional Experience:	Medical officer in PSRO program, Division of Peer Review, Bureau of Quality Assurance, Health Services Administration, U.S. Public Health Service, Department of HEW, Rockville, MD. Aug 1974-Jan. 1975. Director, MEDEX Northwest Division and Assistant Professor, Dept. of Health Services, School of Public Health and Community Medicine; Adjunct Assistant Professor, Dept. of Medicine, School of Medicine; University of Washington, Seattle, WA. August 1977-November 1980. Deputy Director of Public Health, Maricopa County Dept. of Heath Services, Phoenix, AZ. December 1980-November 1982. Director of Public Health and Health Officer, Maricopa County Dept. of Health Services, Phoenix, AZ. November 1982-December 1985. Chairman, Department of Community Medicine, Maricopa Medical Center, Phoenix, AZ. December 1980-December 1985. Adjunct Associate Professor, Dept. of Family and Community Medicine, University of Arizona School of Medicine, Tucson, AZ. 1981-85.
Specialty Board Certification:	General Preventive Medicine, 1979.
Specialty Board Eligibility:	Internal Medicine, 1973
Organizations and Memberships:	Association of State and Territorial Health Officials; Executive Committee, 1987-1990. National Association of County Health Officials; President, July 1983-Dec. 1985. Physicians National Housestaff Association; President, 1974-76.

HIV/AIDS

Senator HARKIN. Thank you very much.

Thank you all very much for very succinct and to the point statements. I just have a few questions that I will ask initially, and then we will go down the order in which Senators appeared.

Dr. Mason, the administration's request was $1.695 billion for AIDS in fiscal year 1991. That is about a 7-percent increase over last year; $66 million is for CDC, $67 million for National Institutes of Health. Several other small increases are offset by a $40 million cut in the Health Resources and Services Administration.

So could you just basically give us an update on AIDS? What are the projections for new cases? What progress has been made in treating it? Why have you dropped funding for AZT, when all the new reports come out showing how effective AZT can be in the early stages?

And what is the focus of the increase in AIDS funds in the various agencies under your control? Just sort of paint us a picture of what is happening.

Dr. **Mason**. I would be delighted to do that, Mr. Chairman. And if I might refer you to several charts that I prepared, and there are handouts at each one of the desks.

AIDS—CURRENT PROBLEM

[Estimated number infected—U.S. approximately 1 million]

	Reported	
	Cases	Known deaths
Cumulative through Dec. 31, 1989	117,781	70,313
1989	35,238	14,544
1988	32,196	18,101

Source: Public Health Service.

The first chart shows the magnitude of the current problem, and I emphasize that the estimated number of infected individuals in the United States is approximately 1 million. The range is 0.8 million to 1.3 million, and this is an estimate based upon studies that are———

Senator **Reid**. Excuse me. We cannot hear. We cannot hear or see. Could you move that a little closer.

Senator **Harkin**. Pull your mike in a little bit, Dr. Mason.

Dr. **Mason**. Thank you, Senator Reid.

Senator **Reid**. Maybe so Senator Adams could see this, could you move that over here? [Pause.]

Dr. **Mason**. I hope you can see that now. The last time I was told people could not hear me I spoke louder and said, is that better? And someone in front said: It is louder, but it is no better. [Laughter.]

We will try to carry on.

Approximately 1 million cases, this is an estimate. So there is an interval there of 0.8 million to 1.3 million based on current estimates. As you know, the Public Health Service has recently revised their estimate downward. We probably were too high 2 or 3 years ago and, as better data becomes available, we are getting it better in line with what is really happening out there.

Senator **Harkin**. That is one of my questions. I will interrupt you right here if you do not mind.

Dr. **Mason**. That would be fine.

Senator **Harkin**. There has been a reduction in that estimate. You say the only reason for that is just better data has come in?

Dr. **Mason**. Better data. Probably with data that was available when the first estimates were made—that was 3 years ago—where we said there was one to 1½ million infected, we were probably high.

It is interesting at that time that various people were estimating as many as 40 million people were infected and CDC came in and said it is only 1 to 1½ million, and there was a lot of criticism that they were too low. But even CDC at that time was higher than what we now feel.

So there has been a slow increase in the number of infected over the last 3 years, and we are not able to measure directly how fast that is, but obviously as a nation it is not spreading like wildfire.

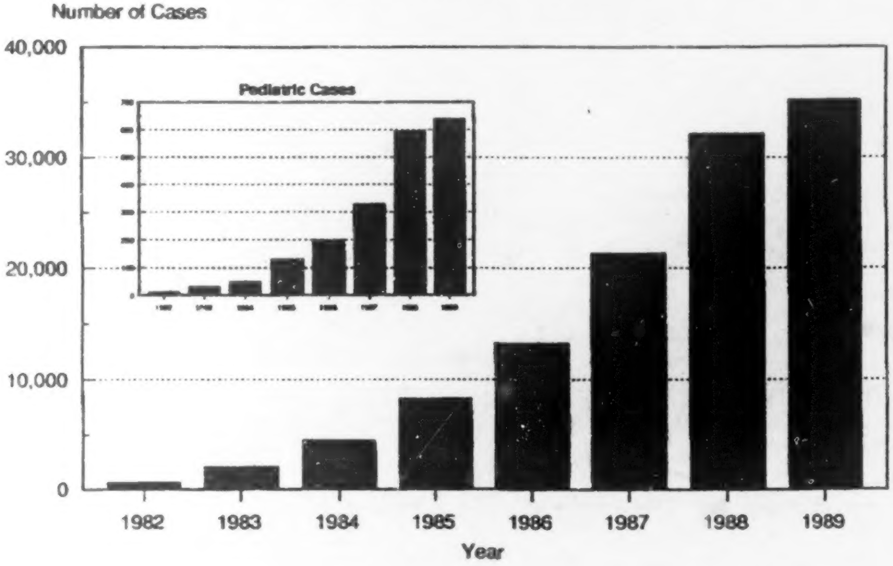
However, among certain risk groups, particularly IV drug abusers and their heterosexual partners, we still estimate that we have rapid spread of this disease. The cumulative number of cases reported through December 31, 1989, is almost 118,000.

You can see that during 1989, 35,000 cases were reported, which represents a 9-percent increase over 1988. There were 640 pediatric cases reported in 1989, and almost 60 percent of the pediatric cases reported are born to mothers who are using intravenous drugs or who are sexual partners of intravenous drug users.

I would like to mention that, in the context of the distribution of these cases that you see on the chart, that a disproportion of those cases are in our minority population: 27 percent among our black population, 15 percent among our Hispanic population, and that is approximately double their ratio in the total population.

We are delighted to report that during 1989, the number of cases associated with blood transfusions fell 12 percent among adults and 39 percent among children. At present, with our careful education of donors, testing and voluntary exclusion, convincing those who are at high risk not to give blood for transfusions, we are beginning to see a significant difference in the number of transfusion-associated AIDS cases.

The next chart, please.


REPORTED AIDS CASES BY YEAR OF REPORT

U.S., 1982 - December 31, 1989

It shows the reported AIDS cases by year of report. And you notice the progression of both total cases as well as in the small inset, the pediatric cases. You notice that there appears to be somewhat of a leveling off in 1989 compared with the rate of increase in previous years. We want to caution you not to jump to any conclusions that the disease is in fact slowing down to that extent.

We are not totally sure why that slowdown occurred in 1989, but there could be, first of all, reporting delays. We know that one large city and a State reported numerous cases right after the end of the year and they will be reported in 1990. So you get artifacts in reporting.

We know that behavior change has occurred, particularly in the white homosexual population, and that started a number of years ago, and this is undoubtedly having some effect in the occurrence of new cases.

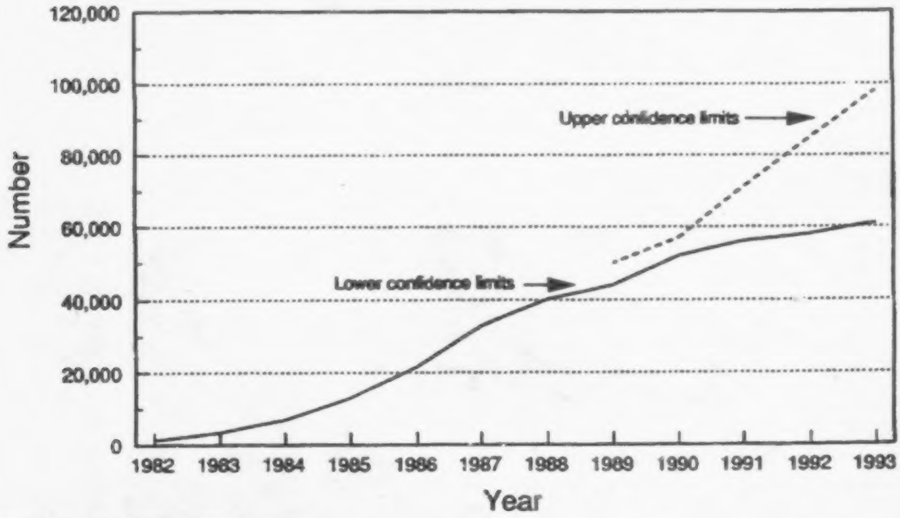
Finally, the use of these new drugs that have been developed by biomedical research and rapidly licensed by FDA is also beginning to have an impact, particularly when these are used as an early intervention before symptoms develop. So these people who are infected are slowed down in the progression of their disease, and so the disease is not reported as AIDS.

We think all three of those items are responsible for the trend that is apparent there.

Next chart, please.

PROJECTED AIDS CASES BY YEAR OF DIAGNOSIS *

U.S., 1982 - 1993



* Projections include inflation by 18% in recognition of underreporting to CDC.

Beginning in 1989 an upper and lower range is displayed.

Estimates are based on February 1990 projections.

This again shows what has happened and gives you projections through the year 1993. It is important to emphasize that, since the average incubation period of this disease from onset of infection to where clinical symptoms occur, is approximately 9 years, that all of the cases or nearly all of the cases that will occur between now and 1993, will occur in individuals that are already infected.

Changes in the pattern of transmission in the next 3 or 4 years will not significantly affect the number of cases that will occur.

The next chart, please.

AIDS—future problem

1993—projected range:	
Cumulative cases diagnosed	390,000 to 480,000
Cumulative deaths	285,000 to 340,000
AIDS patients requiring treatment in 1993	151,000 to 225,000

CDC estimates—February 1990.

This shows the projected cases for the year 1993, and by that year the cumulative cases diagnosed will vary between 390,000 and 480,000. By then the cumulative number of deaths will have been from 285,000 to 340,000; and individuals who could benefit from care or treatment will be in the range of 580,000 to 640,000.

This group will be people with symptoms of AIDS, as well as infected individuals who as yet are asymptomatic, but are significantly immunosuppressed, and they can be treated with AZT, aerosolized pentamidine or with other therapies or prophylactic drugs.

The next chart summarizes the research accomplishments of the past years, the investment in biomedical science. I will not read each of those lines, but you can see that the research accomplishments are indeed significant. Things are coming out of the pipeline that are having a very meaningful effect.

The next chart shows approved AIDS drugs and the indications for which they are used. And again, I think this is very impressive in terms of what has been accomplished. Of course at the top of the list is Zidovudine or AZT, which is effective in suppressing HIV, the retrovirus that causes the disease.

The other drugs are useful in treating or preventing the opportunistic infections that occur in people with AIDS because they have been immunologically compromised.

The next chart simply summarizes prevention accomplishments, and for example, under the third bullet, expanded counseling, testing, and partner notification programs, more than 2 million Americans have been tested in public sites since 1985 as a result of these prevention programs.

We know today that the public's knowledge about HIV infection and how it is transmitted has increased significantly. There is more knowledge out there and there is less disinformation.

We are now concentrating on targeting information particularly to those groups whose behaviors put them at risk.

The next chart shows annual deaths in the United States from selected causes. I include this chart because I think it puts HIV infection in perspective. We have to remember that the reported number of cases here increased to 44,000, to adjust for the approximately 18 percent that are not reported. It shows in the context of deaths what is happening.

Many ask, if that is all the deaths that are occurring, why are we spending so much, why are we so concerned about HIV infection? I just wanted to mention that we are spending as much as we are because the epidemic continues to grow.

Although we are concerned about the other diseases on the chart, most of the rates in the context of tobacco-related illness or diet-related illness and these other things are relatively stable, while with HIV infection we are dealing with an epidemic, and if we do not get on top of that we will pay for it later.

We need to invest now. We need to develop information that has never been available.

Finally, this is a fatal disease, not to say that other diseases on the chart are not fatal. We also have great spinoff benefits from what we are now learning in the context of biomedical research into the cause of AIDS. Had it not been for good cancer research, we would not have as rapidly identified the cause of HIV or we would not have a diagnostic test.

A lot of the drugs, like AZT, were previously screened in the context of cancer chemotherapy. So just as we help to move into the HIV infection because of our investment in cancer and other diseases, what we are investing in HIV will enable us to know more about the immune system, vaccines, and other retroviruses that cause disease in man.

Finally, you asked about new programs and what we are spending. The increase of $109 million that is proposed, which is a 7-percent increase, will allow FDA, for example, to increase the rapidity with which they review, evaluate, and approve new drugs and, as the backload of new drugs begins to occur as a result of biomedical sciences, provide the staffing so that we will not get behind.

It provides to CDC an increase of $66 million for evaluations to document the effectiveness of various counseling techniques on behavior change. It will enable them to find out more about the rate of spread of this disease.

NIH will have an increase of $57 million or 8 percent over 1990 to fund additional clinical trials, work on vaccine development, and other research activities.

ADAMHA will have an increase of $15 million, or 7 percent, to look at biomedical research, neuroscience, and neuropsychiatric training, risk assessment, prevention activities, buildings and facilities.

The new Agency for Health Care Policy and Research will have an increase of $2 million to expand the AIDS cost and service utilization survey.

And finally, in the Office of the Assistant Secretary for Health, there will be an increase of 11 percent to support minority health grants and AIDS program coordination.

Senator **Harkin**. Dr. Mason, thank you for a very good overview of the whole AIDS program.

How much money are you requesting for pediatric AIDS?

Dr. **Mason**. In total in pediatric AIDS, our increase is $155 million. That represents an increase of $29 million or 23 percent in an important area.

Senator **Harkin**. A 23-percent increase?

Dr. **Mason**. Yes.

Senator HARKIN. It is an important area, because there are a lot of questions being answered on why some babies who are born to infected mothers are infected and some are not.

Dr. MASON. That is right.

Senator HARKIN. Why the differences in the symptoms that they have are different than adults. And there may be some clues there.

Dr. MASON. We want to move treatment much more rapidly into our pediatric population as well.

Senator HARKIN. I just have a couple more before I move on.

I want to talk about preventive health care and health education, which you stressed in your opening statement. Last week I introduced, along with a number of Senators—and I think a few of them are here—the Health Objectives for the Year 2000 Act.

Basically, this legislation gives State and local public health agencies the means to plan and implement health objectives for the year 2000, by increasing the authorization for the preventive health care block grant to $300 million. The funding for this block grant has been frozen at about $85 million for almost a decade.

Could you tell us about your view of the need to increase funding for preventive health care programs and how we might move ahead in the future?

Dr. MASON. We really believe in the primacy of prevention. A lot of diseases that our society is afflicted with today cannot be cured. Many of them can be treated, but it is far better to prevent the disease in the first place.

And we have opportunities for primary, secondary, and tertiary prevention. And because the squeaky-wheel-gets-the-grease syndrome, we tend to put unlimited amounts of money into health care treatments and cures and traditionally we underfund what we could do on the prevention side.

Of course, much of the prevention activities today relate to helping people understand that their own behavior contributes significantly to epidemics of disease that occur. We have talked about HIV infection, but the problem of tobacco in the United States, where we still have almost 400,000 deaths a year—that is more than 1,000 deaths a day—from a disease, a problem, that is totally preventable.

HEALTH OBJECTIVES FOR THE NATION

So we strongly feel that we need to invest in prevention. Now, that is why we have pursued 1990 goals vigorously. You mentioned in your introductory remarks that we had accomplished 50 percent of those goals. We are in the process of working on 1990 objectives and completing that process, and simultaneously since 1987 we have been developing the year 2000 objectives for the Nation.

These year 2000 objectives are not looked upon as a Federal group of objectives, but, since they have been developed from the grassroots up, involving local health departments, State health departments, the voluntary health sector, the private sector, these will truly be national health objectives when they are introduced during the summer of 1990.

What we need to do is make sure that there is adequate strength at the local and State level so that these objectives can be handled, because that is where the rubber hits the road.

We can help in many ways from the Federal level, but there is going to have to be a major effort at the State and local level if we are going to achieve those objectives for the year 2000.

Senator HARKIN. We met half our objectives for 1990. We put in $85 million, roughly, into block grants. Are you saying that if we had perhaps doubled that or tripled that, we might have been closer to meeting more of the objectives that were outlined for 1990?

Dr. MASON. I do not think it is just a matter of dollars—this is going to take a commitment of the public sector and all levels of the private sector. We have got to galvanize the whole Nation to make a more significant commitment.

Senator HARKIN. Can we do it just with rhetoric?

Dr. MASON. No; rhetoric will not get the job done.

Senator HARKIN. That is my question. Thank you very much, Dr. Mason.

I recognize Senator Specter, the ranking member, for any statement or questions.

Senator SPECTER. Dr. Mason, when we take a look at the resources available, and you emphasized commitment at State and local level—if you take a look at the major cities, like in my State, where the health problems are the most acute, they have very little resources to allocate to the tremendous scope of problems that come through on the drug line or on the AIDS line or on crack babies, et cetera.

Given the reality of very little funding which is available at the local level, what is your suggestion? Where can we go from there?

Dr. MASON. This was considered by the Bush budget, and what we tried to do in looking at the overall Public Health Service budget was to put increases into the areas that we felt were of highest priority.

With budget deficit reduction, we would like very much to be able to augment those things that we are doing, but the Bush budget recognizes those problems that exist. It recognizes opportunities and, within the limits of our budget ability, tries to fund those areas that are of highest priority.

Senator SPECTER. Well, that is a very generalized answer, and I do not know that any more can be done. You take a look at the millions of people not covered by health insurance, health care, and the billions of dollars in costs. The President has now charged the Secretary of Health and Human Services with the responsibility to come up with a program for the country.

AREAS OF HIGHEST PRIORITY

Do you have any insights as to how we can begin to give the necessary coverage, given the tremendous costs involved and the budget constraints?

Dr. MASON. I mentioned in my statement earlier those areas where we were increasing or requesting an increase related to minority health, because minorities disproportionately have disease problems. We requested an increase in funding for prevention of infant mortality, because this Nation needs to galvanize its effort in that area.

So sprinkled throughout the over $480 million increase in the Public Health Service budget are targeted increases in areas where we feel we can make the greatest difference. Minority health and infant mortality are two specific areas where we would like to provide increased access.

I think the Secretary is also exceedingly interested in pursuing the outcome of the Horner task group that he appointed Under Secretary Constance Horner to, to take a look at this whole area of health care financing, access, long-term care, the Quadrennial Social Security Commission. And Dr. Sullivan has been requested to look at the recommendations that come from within the Department of Health and Human Services, plus these other studies that are being put together, and bring back recommendations as to how we can provide access and emphasize those preventive services.

I see that rolling out in the next 6 to 9 months.

Senator **Specter**. Well, I see your allocations as you see the areas of greatest need, and of course this subcommittee will lend its efforts along the same line. But it is a continuing problem to find enough funding to take care of the tremendous needs.

What kind of a timetable do you see on the response by the Secretary of Health and Human Services to the request and the charge by the President to come up with an overall plan?

Dr. **Mason**. The Horner task group is working on a deadline of having their recommendations together some time this summer. The Quadrennial Social Security Commission is also looking for a summer-fall date.

The Secretary, as a result of the President's State of the Union Message, is putting together a timetable as to when he can have access to these various studies as they are presented, and I have not yet heard of the date that he is expected to make his report.

Senator **Specter**. Do you think it will be done by the end of the year?

Dr. **Mason**. I would hope so, but I just do not know. It depends on when he is able to obtain the reports that are coming forth.

Senator **Specter**. Thank you very much, Dr. Mason.

Thank you, Mr. Chairman.

Senator **Harkin**. Thank you, Senator Specter.

Senator Bumpers.

RESEARCH FUNDING LEVELS

Senator **Bumpers**. Dr. Mason, how many grants could you make, good grants, if you had the money? You said you made 22,842 last year.

Dr. **Mason**. What we are doing is, as the peer review system goes into effect and grant applications are reviewed by these peers, we then rank them according to their promise, and then we fund insofar as there is money available to fund them. At NIH they are funding at approximately the 20-percent level. In other words, 20 percent of those grants that are approved by the peer review committee get funding.

So you could go up that on a priority basis higher than where we are today.

Where are you at ADAMHA?

Dr. **Goodwin**. About the same.

Dr. **Mason**. About the same, about 20 percent funding level.

Senator **Bumpers**. I spent a day at NIH last year and Dr. Wyngaarden suggested to me that they probably had anywhere from four to six applications for every one that they could grant. Is that a fair statement or not?

Dr. **Mason**. Well, I said 20 percent, so that would be 5 to 1. It is in that same area.

Senator **Bumpers**. Well, I note that virtually all of your increase of $400 million plus is in research. In other words, you are asking for $400 million in research, and you are asking for a total of about a $460 million increase for the entire Department of $13 billion some.

Is that a fair statement? I know you are cutting some things in order to get there.

Dr. **Mason**. There are cuts, and so that is a fair overall statement.

Senator **Bumpers**. And others get increases, too, but I am saying you are obviously concentrating on that.

Dr. **Mason**. We feel that it is absolutely essential that we maintain the Nation's biomedical establishment, for the reason that we just cannot afford to do less. Quality of life, the health of Americans, not just Americans but worldwide, and finally, to maintain the competitive edge of the United States, our balance of payments. We need to fund biotechnology to maintain our competitive edge there.

Senator **Bumpers**. How are we doing at the U.S. Patent Office compared to the Japanese in biomedical patents?

Dr. **Mason**. I do not have that. Fred, do you have a figure on that?

Dr. **Goodwin**. No; we could get that information for you.

Dr. **Mason**. We could provide that.

Senator **Bumpers**. Would you, please.

Dr. **Mason**. We would be happy to.

Senator **Reid**. Could you supply that to each of us?

Dr. **Mason**. Indeed.

[The information follows:]

BIOMEDICAL PATENTS

According to the Department of Commerce U.S. Patent and Trademark Office there are no exact numbers on the number of biomedical patents issued to the United States and the number to Japan. A 1989 study issued by GAO states that the percent of patents issued to the United States for the period 1963–87 for molecular biology was 57 percent and for the Japanese was 18 percent. The study also stated that of the percent of patents pending for 1988 57 percent was for the United States and 14 percent was for the Japanese. The U.S. Patent Office estimates that the percent of patents issued for 1988 for the Japanese will be about 16 percent.

AIDS TESTING

Senator **Bumpers**. Back to AIDS, Dr. Mason. You mentioned a moment ago that the manifestation of the symptoms is usually around 9 years after infection.

Dr. **Mason**. That is right, on average.

Senator **Bumpers**. But as I understand it, we still are not doing a very good rate in testing to know early on whether somebody is infected. In other words, somebody could have AIDS for 4 or 5 years and it still might not show up in the test that we now use. Is that correct?

Dr. **Mason**. That is correct.

Senator **Bumpers**. Are we making any progress in being able to make an earlier HIV-positive determination?

Dr. **Mason**. There are two reasons why a person that has participated in high-risk behavior—sexual behaviors, intravenous drug abuse behavior—why it would be in the best interest of both the individual and society for them to be tested.

The first is, if a person does not know if they are positive or not, they may be unknowingly transmitting the disease to others, and if they recognize that they are positive then they would, with help through counseling and encouragement——

Senator **Bumpers**. And maybe AZT treatment at an earlier period of time.

Dr. **Mason**. And that is the second reason, is it would be medically useful for an individual who is HIV-positive to be followed clinically. He ought to have a T-cell determination to see how much immunosuppression is going on, and there are certain drugs that are available that can be used as early interventions to stop the movement of the individual from asymptomatic to symptomatic.

INFANT MORTALITY

Senator **Bumpers**. Dr. Mason, I get depressed at times like this: 22d in infant mortality; AIDS cases that far surpass any other nation, at least any of the developed nations, drug problems that just seem to be intractable, and a health care system that has no coverage for 37 or 38 million people.

All those things are profoundly disturbing to me, a great patriot who likes to get out and make speeches on how we are the greatest Nation on Earth. And on top of that, I keep making this statement: It shocks me—it does not seem to shock anybody else—that within 10 miles of where you sit there were more murders last year than in all of Western Europe and Japan combined.

So I really am concerned about the future of our country. I have been proceeding along the assumption that we were 17th or 18th in infant mortalities. You say we are 22d?

Dr. **Mason**. That is the current ranking.

Senator **Bumpers**. And how does that compare, for example, with 5 years ago?

Dr. **Mason**. Basically, I should say that the data between nations are not entirely comparable. So if there is a difference in 18th and 22d, it probably is not significant because of the variation in the way the statistics are compiled.

But we have about held our own in terms of being somewhere between 18th and 22d.

Senator **Bumpers**. And yet we spend more on health care than any nation on Earth per capita, is that not correct?

Dr. **Mason**. That is correct.

VULNERABILITY FACTORS AND DRUGS

Senator **Bumpers**. And when it comes to drugs, Dr. Goodwin, it seems to me that the President and an awful lot of other people talk about everything under the shining Sun on the drug problem except the basic problems of drugs, and that is poverty and low self-esteem, and those two are connected, too.

Is that a fair statement?

Dr. **Goodwin**. Well, I think those conditions are more likely to bring out other vulnerability factors. I think there is a combination of those kinds of environmental factors with psychological factors that make a particular individual vulnerable.

For every poverty situation which has victims, we also know of remarkable stories of people who survive it and get out of it, and we have to understand both.

Senator **Bumpers**. Well, that is government by the exception, though, rather than the rule.

Dr. **Goodwin**. What I am saying is that you have to understand both individual and environmental vulnerability factors. Although the drug problem has shifted more to the problem of addiction, the majority of people who live in the inner city are not addicted to drugs. So we have to remember that majority are not addicts and focus on——

Senator **Bumpers**. But a lot more people who make over $50,000 a year, and a lot more people who are college graduates do not use drugs, too; is that not correct?

Dr. **Goodwin**. That is right, and the concentration is in the poverty areas. And I agree that those are very important factors, and I think that the health approach for which we are responsible has to take them into account.

Our main focus is a health focus—that is, trying to understand how people are vulnerable to addiction and, once they get addicted, how it in fact reinforces itself.

ALCOHOL EDUCATION PROGRAM

Senator **Bumpers**. Dr. Goodwin, we have talked a lot about AIDS here, and let me just shift to alcohol. I saw a story in the New York Times the other day that was fairly alarming to me, and that was that 2.7 of every 1,000 births in this country are alcoholic syndrome children, and among Navajo and Hopi women it is as high as 10 per 1,000 births.

My question is, while the degree of that problem may not be as profound, for example, as AIDS and crack babies and all that sort of thing, it seems to me that that is a significant number, and that with a really good education program it can be reduced rather dramatically.

Would you comment on that?

Dr. **Goodwin**. I think the efficacy of education programs in those kinds of populations require that they be culturally specific. There have been considerable effects, good effects, of education programs in prevention among Indians, and that is just getting started in an accelerated way.

However, for every success in a prevention program one also has to pay attention to the people who drop out of those programs and the more severely addicted. We know, for example, in the most severe forms of addiction to alcohol, that is alcoholism, there are important genetic factors. And the point about prevention is to separate those people that are amenable to broad education from those who need real clinical treatment of their addiction potential.

The other factor is that alcoholics who also have a mental disorder are much more likely to go on to become destructive drinkers than those who do not. So it is a complex quilt. There is no one answer, and I do not mean that as a glib response, but rather that we have to integrate individual clinical approaches with the broader social and educational approaches.

Up until recently, that has not been done. Frankly, you have had people out there doing their education bit and people doing other kinds of prevention programs, and then the people working in the clinical sphere, where they look at each person as an individual.

The effort that we are trying to make is to get those different traditions to be integrated.

HIGH SCHOOL SURVEY

Senator **Bumpers**. I recently looked at the high school senior drug survey that showed that drug abuse among high school seniors has been declining since about 1986 or 1987, somewhere along in there.

Dr. **Goodwin**. For those who stay in high school, not the dropouts.

Senator **Bumpers**. Yes; I am not going to pursue that because I pursued that with somebody else the other day. But that is something that is not addressed by the report, I think, and that is it does not include the dropouts and that is where the prevalent drug abuse is.

Dr. **Goodwin**. Right.

Senator **Bumpers**. But that is really not the point I was driving at.

But that same study showed that 35 percent of the high school seniors in this country said that they had had five or more drinks in a row in the past 2 weeks. Now, that really knocked my socks off. I could not believe that high school seniors, every 2 weeks, were having five drinks in a row.

Is that up, down, or what?

Dr. **Goodwin**. There is a slight decrease in that abusive drinking.

Senator **Bumpers**. My God.

Dr. **Goodwin**. It is nowhere as dramatic as the illicit drug decrease. The decrease in abusive drinking by high school seniors is only about 10 percent over the last 3 years. So it is still a very severe problem.

Senator **Bumpers**. The chairman says it was probably worse than that when he was in high school.

Go ahead.

Dr. **Goodwin**. One of the things that has been speculated about in the alcohol treatment community is—and this is particularly true related to the schools—is that there has been, perhaps until recently, some reluctance by school authorities to be authoritarian or to be in loco parentis in the old traditional way.

There has been an awful lot of erosion of the ability of school officials to police what students do at parties. This is particularly true of college campuses, where you will find that many colleges have absolutely no effective policy to control drinking in their dormitories.

We appreciate the effort that the Congress has made to put some teeth in various laws that require colleges and other institutions to have really meaningful antidrug and alcohol policies in their dormitories.

Senator **Bumpers**. Well, Mr. Chairman, let me just conclude—excuse me.

Senator **Harkin**. Can we have the CDC and HRSA and ADAMHA go? The first round of people were people who had general questions of Dr. Mason.

Senator **Reid**. Mr. Chairman, this is a very interesting hearing. I am sorry I am not going to be able to stay and listen to everyone.

But I am forever amazed at the magnetic power of the Office of Management and Budget. It seems that they have this ability, when you come here you suddenly do not need money for anything.

I am, like Senator Bumpers—I think depressed is also about the best word I can come up with now, to listen to what goes on. And I think that if you gentlemen had a little more of a loose line, a little longer leash, that you would probably be a little more candid and tell us about how much more money is needed in various places.

I think that we have to recognize that we have to spend more money in some of these areas. I was with Senator Bumpers last year when he offered an amendment to bring, what was it, 2,000 troops home from Korea, which would save us millions of dollars, which could be used in programs under this subcommittee's jurisdiction.

So I would hope that during these hearings you will be more assertive in the fact that we need to spend more money on these programs. I would be very interested in seeing the original budgets that you submitted, all of you, to OMB. I would bet and hope that they are different than the ones that we are going over now.

I first of all want to tell you how much I respect and admire the work that you do, you have dedicated your life, and the panel that will follow, to government service. I appreciate that.

POTENTIAL LIST OF CLINICAL CONDITIONS

Now, some specific questions. I have received a table that is entitled "Potential List of Clinical Conditions to Consider for HCFA Effectiveness." Dr. Mason, looking over those lists of approximately 40 conditions, I note that there is nothing listed for inflammatory bowel disease. Is that right?

I mean, that is right. I can read it. It is not there.

Dr. Mason: Are these the priority areas for the Agency for Health Care Policy and Research?

Senator **Reid**. Yes.

Dr. **Mason**. I do not think there is anything on our priority list for inflammatory bowel disease.

Senator **Reid**. I am particularly interested in that for some personal reasons, and I am looking over the diseases of the gastrointestinal digestive system. And I would like whoever established this list to look into why things like a hiatal hernia is listed higher than ulcerative colitis, Kron's disease, and some of the other things.

So if somebody could give me, not now, but some indication of why inflammatory bowel disease is not listed as something that should be looked into.

Dr. MASON. We would be very happy to submit that to you.

[The information follows:]

POTENTIAL LIST OF CLINICAL CONDITIONS TO CONSIDER FOR HCFA EFFECTIVENESS

The referenced list was developed by the Institute of Medicine (IOM) in response to a request by HCFA.

The IOM established critical factors for identifying clinical conditions deserving priority attention for HCFA-oriented effectiveness research. High prevalence of the disease, the burden of the illness in the elderly, and substantial variation in the treatment of the disease are illustrative examples of those critical factors.

Using these criteria, inflammatory bowel diseases, therefore, were not highlighted as a high priority to the HCFA effectiveness research effort.

At this time, however, our Medical Treatment Effectiveness Program (MEDTEP), responds to all populations, not just the elderly. Therefore, researchers could identify inflammatory bowel diseases as a research topic if they meet the full criteria specified for the NEDTEP research program.

Dr. MASON. And let me just say generally that you have to start somewhere in developing criteria, and both the Health Care Financing Administration and the Public Health Service have selected these with the help of the Institute of Medicine, because they seem to be the most promising beginning point in terms of what could be contributed to the quality of medicine in America and those things that seem to have major geographical differences, or where there are multiple therapeutic modalities, where you could compare one with the other.

So it is a starting point, and we will give you those criteria that have been used, and perhaps how soon we can move beyond this list to other diseases.

Senator REID. I am not going to go into this any further, other than to say that hernia really does not list, at least in my mind, as something that is on the same plane as inflammatory bowel disease. But whoever is going to get back to me could talk to me about that.

Dr. MASON. Excellent.

Senator REID. I am also interested in why I have not seen in the material that I have reviewed more on chronic fatigue syndrome, the Epstein-Barr. And I again would ask somebody to direct their attention to that and inform me what, if anything, is being done by any of the agencies regarding that disease.

Dr. MASON. We would be delighted to provide information. Both the CDC and NIH have been looking at that situation, and we will summarize that for the record.

[The information follows:]

Chronic Fatigue Syndrome
(Dollars in thousands)

	1988 Actual	1989 Actual	1990 Estimate	1991 Estimate
CDC . .	$407	$1,200	$1,250	$1,250
NIAID .	$988	$1,472	$1,531	$1,595

Centers for Disease Control (CDC)

In FY 1989, CDC implemented a surveillance system in four areas of the United States (Atlanta, Georgia; Kent County (Grand Rapids), Michigan; Sedawick County (Wichita), Kansas; and the Reno-Carson City metropolitan area, Nevada). This surveillance system is designed to: 1) identify person in these areas who have chronic unexplained fatigue, 2) carefully evaluate each for evidence of preexisting chronic conditions that could be causing their symptoms, 3) determine if each fulfills the published Chronic Fatigue Syndrome case definition, 4) monitor the annual incidence and the prevalence of CFS in the four areas, 5) identify patterns of symptoms and their timing relative to CFS. Approximately 200 physicians have been recruited to participate in this surveillance system. The CDC has completed interviews and medical record reviews of 20 CFS patients in Atlanta for whom the diagnosis of CFS could be assessed, provided laboratory support for a study of patients diagnosed with CFS in Massachusetts to assess a reported association of CFS with chronic enteroviral infections (no association was identified), and developed a CFS fact sheet for responding to public inquiries (about 5,000 inquiries were received during FY 1989).

The initial review of a sample of CFS cases in Atlanta underscores the importance of CDC's focus on case definitions in correcting a major flaw in CFS research and to improve future communications. The review has led to the decision to try to formally link a study of cases and controls to the surveillance and followup system in Atlanta where each case-patient's status can be evaluated by a panel of expert physicians. It also underscores the importance of publicizing the appropriate laboratory tests for suspected cases of CFS. CFS cannot be diagnosed by Epstein-Barr Virus serologic tests, and that it remains a diagnosis of exclusion. This message should reduce morbidity from potentially treatable conditions which are currently being misdiagnosed as CFS or Chronic

Epstein-Barr Virus (CEBV). For appropriate management, CDC emphasized symptomatic treatment, healthy life style, appropriate reassurance, avoidance of potentially dangerous therapies that lack scientific justification and periodic reevaluations of the diagnosis.

CDC will develop methodologies for evaluating the type and onsets of neuropsychological abnormalities as well as the type of fatigue in patients with CFS and to apply these methodologies to patients identified in the pilot surveillance; initiate a case-control component into the surveillance system in Atlanta designed to look for associated immunologic findings in patients with CFS and risk factors for the development of CFS; and investigate suspected clusters of CFS that may be reported to CDC in order to better delineate this illness, clinically, virologically and epidemiologically.

National Institutes of Health (NIH)

Chronic fatigue syndrome (CFS) is a multisystem syndrome characterized by months of debilitating fatigue frequently associated with recurrent sore throat, low grade fever, myalgia, headache, gastrointestinal symptoms and tender lymph nodes. Currently, the public health significance of CFS cannot be fully assessed without data on the prevalence of the syndrome and knowledge of its natural history. Furthermore, therapies cannot be evaluated without clinical or laboratory markers of disease remission and without appropriate controls. Determination of the cause and mechanisms of pathogenesis require clinical and epidemiologic studies that incorporate well-defined cases and controls.

Aware of the dearth of scientifically sound information about the prevalence, incidence and cause(s) of CFS, the NIAID began to encourage research into the etiology and epidemiology of CFS with the organization of a workshop in 1985, the issuance of a Program Announcement in 1987, and the organization of a second workshop in 1988 that focused on research design and clinical definition.

The NIAID is currently supporting 4 studies (1 intramural, 3 extramural) which collectively address the most pressing research questions concerning CFS, such as prevalence, diagnosis, laboratory and clinical markers, natural history and prognosis.

The NIAID's long-term intramural study, with more than 150 CFS patients enrolled over time, is concerned with clinical evaluation, treatment, and understanding the biology of the syndrome. Investigators from the National Cancer Institute (NCI), the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Child Health and Human Development (NICHD) have collaborated in studies of this intramural CFS patient group.

Current NIAID extramural studies include:

o A blinded, case-control study of CFS patients, looking for laboratory correlates -- especially those related to Epstein-Barr virus (EBV) --- for diagnostic and prognostic purposes.

- A study of factors that control reactivation of EBV which has already led to the identification of the gene sequences responsible for reactivation of EBV form lymphocytes, and has reported a specific EBV immunologic defect that my be significant. Research into the mechanisms underlying these findings and the possible significance in CFS patients is ongoing.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

EPSTEIN-BARR VIRUS
(Dollars in thousands)

	1986 Actual	1987 Actual	1988 Actual	1989 Actual	1990 Est.	1991 Est.
NCI	$6,493	$6,528	$6,357	$9,199	$9,456	$9,920
NHLBI . . .	---	547	515	533	550	575
NIDR . . .	905	1,828	1,925	1,992	2,064	2,140
NIAID . . .	2,911	4,259	4,090	3,784	3,870	4,083
NIA	---	---	107	307	318	330
NIAMS . . .	640	501	931	779	810	852
DRR	304	298	235	263	245	212
TOTAL, NIH	11,253	13,961	14,160	16,857	17,313	18,112

CHILD VICTIMS' RIGHTS

Senator **Reid**. Mr. Chairman, I have been working the past couple of years on child victims' rights. I have great interest in seeing the victim treatment, sex offender treatment programs have more attention directed toward them. Under the Mental Health Act of 1988, I understood there was supposed to be something done in this regard.

Do you know, Dr. Goodwin, if your agency plans anything regarding treatment programs for this condition?

Dr. **Goodwin**. I would have to get that for you, but there are activities in that area in the research budgets. I am not sure about the treatment program.

In programs of the Office for Substance Abuse Prevention, a number of the community prevention demonstrations include child abuse, because child abuse is very frequently associated with substance abuse.

[The information follows:]

MENTAL HEALTH DEMONSTRATION PROJECTS

The Congress authorized a number of mental health demonstration projects in Public Law 100-690: "Anti-Drug Abuse Act of 1988". Specifically, this law authorized "demonstration projects for treatment and prevention relating to sex offenses" under section 520A.(a) of the PHS Act and "prevention services demonstration projects" under section 520A.(b). Conferees on the appropriations bill for fiscal year 1990 indicated that up to $4 million should be used for subsection (b) prevention demonstrations and subsection (a) youth suicide prevention demonstrations. No funds were identified for subsection (a) treatment and prevention projects relating to sex offenses.

However, the National Institute of Mental Health (NIMH) recognizes the importance of sex offense prevention and treatment to our public health mission and has an active research program in this area through its Antisocial and Violent Behavior Branch in the Division of Biometry and Applied Sciences. Supported with general research funds, this area currently receives almost $1.5 million for research of high scientific merit. One recently funded grant to the California Department of Mental Health, for example, under NIMH's initiative to enhance the capacity of State mental health departments to conduct research, is designed to strengthen that Department's evaluation of an innovative treatment program for sex offenders which is based on a relapse prevention model of treatment. This project should provide important new information of national significance on whether treatment can prevent recidivistic sex offenses.

Other noteworthy studies address classification schemes for rapists and child molesters, diagnostic assessments and outpatient treatment for child molesters, prediction of aggressive behavior toward women, evaluation of a curriculum for teaching young children how to prevent sexual victimization, and treatment of rape victims.

The NIMH also will soon issue several new requests for applications (RFA) for prevention demonstrations. These RFA's will emphasize prevention demonstrations for child and adolescent mental disorders (such as conduct disorders), infants at high risk for future mental health problems, and youth at risk for suicide. In addition, NIMH will also initiate an RFA for community-based crisis intervention and case management demonstrations to prevent hospitalization of the chronically mentally ill. This effort will give priority attention to the special problems encountered by rural mental health delivery systems. While these areas constitute only several of the Institute's priorities, we believe they are critically important, timely, and, as indicated recently by Congress, merit special attention.

ADVANCES IN CANCER RESEARCH

Senator **REID**. We have talked a lot here this morning about AIDS. I would be interested in hearing from you, Dr. Mason, as to what has happened on a positive nature this past year regarding cancer research, if anything?

Dr. **MASON**. I think that there have been a number of developments in the field of cancer research, both in the epidemiology, the prevention, as well as treatment modalities. In the context of our presentation on AIDS and HIV infection, we gave a list of things, but that is only indirectly related to cancer per se.

I would think that on the hearing with the National Institutes of Health they would have detailed information on that, and I would be happy to get anything for the record on specific advances, because they have been significant in the past few years.

[The information follows:]

MAJOR RECENT ACCOMPLISHMENTS OF THE NATIONAL CANCER INSTITUTE

A historic gene transfer occurred this year at the NCI with two NCI scientists and one from NHLBI inserting new genetic material into human cells as an important step in creating gene therapy;

Adjuvant therapy was established as saving the lives of advanced colon cancer patients with early breast cancer, bladder, and head and neck cancers. Developed new diagnostic tests for specific subsets of breast cancer patients who would benefit;

It has been found that certain genetic abnormalities play an important role in the genetic events that culminate in lung cancer;

It has been shown that an accumulation of complex genetic alterations is associated with the progression of colorectal tumors from benign adenomatous polyps to frank carcinomas. This lays the groundwork for new diagnostic, prognostic, and treatment of colorectal tumors;

NCI scientists have discovered several proteins that my be involved in positive and negative regulation of tumor invasion and metastasis. These include the laminin receptor, autocrine motility factor, NM23 metastasis suppressor protein, type IV collagenase, and the newest discovery TIMP-2 metalloproteinase inhibitor;

Scientists at Frederick Cancer Research Facility have made several discoveries about the AIDS virus that take important steps toward developing a vaccine;

Using this supercomputer, the crystallographic structure of the HIV-1 protease has been created;

New insights into the human papilloma virus and its attack on suppressor cells in the development of cervical cancer—similar process at work in squamous cell cancer of the oral cavity;

NCI and FDA have embarked on joint programs, regular meetings and other actions designed to speed drug development in cancer and AIDS;

It has been found that high testosterone levels are related to prostate cancer—as is a high-fat, inadequately nourishing diet;

The Cancer Centers are being redirected and will add more community service and outreach activities and more participation in high priority clinical trials;

Investigational New Drugs were filled for 8 drugs (3 AIDS) and 11 new biological response modifiers; and

Recent discoveries have demonstrated that the *N-myc* oncogene is amplified in the neuroblastomas of pediatric patients and that the HER-2neu oncogene has been confirmed in both breast cancer and ovarian cancer.

ACCESS TO HEALTH CARE

Senator **REID**. One last thing, Mr. Chairman.

Senator Bumpers talked about preventive measures. In my office just a short time ago was one of the physicians that works in the largest hospital in Nevada, a place called Sunrise Hospital. He is in the neonatal unit. In fact, he established that.

He indicated that 30 percent of the babies in that unit are there as a result of lack of care prior to their having the babies, the mothers having the babies, indicating to me that in the relatively small area of Las Vegas that millions and millions of dollars in health care each year could be saved if especially teenage pregnant women would get some minimal care.

Dr. **MASON**. You have put your finger on what is one of the major problems in the United States in why we rank 22d. There of course has to be access. If a woman has no access to health care services, then of course the likelihood that she will deliver a low birth weight baby or a baby that is impaired in some way is very high.

But in addition to access, we need to have outreach. We need to simplify our programs through programs like one-stop shopping. And we are proud that a $63 million increase in our 1991 budget request is specifically to look at services in our community and migrant health centers, one-stop shopping, infant mortality case management, mom vans to go out and bring those women in, so that we will not have those additional expenses later.

The Indian Health Service, that was brought up by Senator Bumpers, some of the problems with fetal alcohol syndrome. We are proud that over the last 20 years the infant mortality among American Indians and Alaskan Natives has come down from over 67 deaths per thousand births to where it is now roughly what it is for the rest of the nation.

Now, Indian Health Service will get an additional $11 million to concentrate on efforts on fetal alcohol syndrome and other problems. But it shows when you put together access with outreach that we can just have miraculous changes in infant mortality, and in the long run it saves money.

Senator REID. Thank you, Mr. Chairman.

Senator HARKIN. Thank you.

Senator Adams.

RURAL DRUG USE

Senator ADAMS. Thank you, Mr. Chairman.

Thank you, Dr. Goodwin and Dr. Mason. Dr. Goodwin, I am going to ask you some specific questions about problems that are involved in our State, and in particular with the research ideas that you have set forth on pages 5 and 6 involving dopamine, the chemical messenger to the brain excessively active in schizophrenia.

Before doing that, I want to indicate to you that I share the chairman's concern of the rapid rise of the use of rural America to develop designer drugs and to distribute them. In my State in particular, the city of Yakima has been used as a distribution point for black tar cocaine—I mean, black tar heroin, for cocaine, and for other drugs.

Now, I am going to ask you first a couple of questions. Any of you can answer these, but I am directing these to Dr. Goodwin because he mentioned these in his paper. It is my understanding, but please correct me—what is crank, and is it the same thing as ice, and is it a methamphetamine?

Dr. GOODWIN. Yes. Yes; those are all synonymous.

Senator ADAMS. They are the same thing?

Dr. GOODWIN. Yes.

Senator ADAMS. This is now moving through our State at a rapid rate following crack, and what I am concerned about is, you indicate here in your paper on the last page, page 7, "crack cocaine is one of the most addictive substances yet known and, because of the uncontrollable craving for cocaine, abusers tend to strongly resist available treatments."

Then you indicate a particular chemical. Is this same kind of research being done so that the shift to ice and these other, whatever these other things are called, so that it does not get as far ahead of us as crack?

Dr. GOODWIN. Much of the research on brain mechanisms overlaps. And you mentioned dopamine systems.

Senator ADAMS. As I understand, all these affect dopamine transfer between the centers of the brain and production centers, and they either exhilarate it or depress it and maybe sometimes burn it out. Is that generally——

Dr. GOODWIN. That is a very good summary of it, actually. The differences between methamphetamine and crack cocaine mostly relate to the duration of action. Methamphetamine stays in the brain for a much longer period of time, 8 to 12 hours, so the high that methamphetamine produces is a longer, smoother high, if you will, although it produces more irritability and aggressive feelings and a sense of restlessness, much more than you get with crack cocaine.

Senator ADAMS. The reason I am indicating this to you is that in my State alone the number of illegal labs on that that were busted went from 4 in 1984 to 93 in 1988, and we do not even have the figures in 1989, and we are ranked fourth in that.

A great deal of this is apparently being done in rural areas, is that correct?

Dr. GOODWIN. Yes; and this, by the way, points up what Senator Harkin said earlier, and that is that, although interdiction efforts are important for those drugs that come in from outside, interdiction efforts will have no impact on home-grown products.

RURAL DRUG TREATMENT

Senator ADAMS. That is why I want to emphasize treatment. I asked these questions first to go to what my real question is, and my hopeful response from all of you. We have this problem and local resources are not doing the job. I happen to be involved in two areas:

My home State, which is the problem in Yakima, and it spreads into the whole I-5 corridor; and I am also chairman of the D.C. Subcommittee on Appropriations, and we have appropriated money and we want to appropriate more money for treatment and education.

Now, can you describe to me what type of treatment program we can use if we can stabilize the streets in the District of Columbia and interdict or stop the movement through some of our rural centers—and I happened to mention one city; there is another city that it is growing in rapidly—that will do something with those who have this form of addiction?

Because from your paper what I am discouraged about—and I have been through the ADAMHA facilities you have in Seattle on alcohol and so on. They are excellent. I mean, the people know what they are doing, there is a detoxification program, there are so many days spent there, try to get them into Alcoholics Anonymous.

But I found in this city and elsewhere that when we are dealing with crack, and what I am afraid you are telling me, and tell me if I am wrong, is going to be the effect of ice and crank, we do not have a handle through research on what we do with these people.

Dr. GOODWIN. Well, I cannot speak specifically about the rural areas in Washington, although I can say, by the way, that the treatment programs in Seattle are some of the best in the country, as is the research.

Senator ADAMS. The alcohol program is excellent, and they do treat drug people, too.

But I would just state to you what the director says to me there. He says that we can bring in a crack addict and can detoxify that person in 48 hours, as opposed to a much longer period of time for alcoholism, but it does not have any effect.

I mean by that they are back out on the street, the craving returns, and they either do not come back or they cycle.

I think this committee is interested—I know I certainly am and I think the whole Congress is—in if we cannot treat these people, reduce the craving, deter them in a way, then we have got to incarcerate them. And we have tried that, too. I just would like to know where we are between treatment, incarceration, and research.

Dr. GOODWIN. Well, I think there is a variety of things that are important to say in regard to this. One is, with the ice or methamphetamine epidemic, the National Institute on Drug Abuse is much further ahead on this then it was with the crack epidemic. They have had investigative teams in Hawaii, where the initial wave started, and the other places in the west coast.

There is nothing yet that has been seen in the Midwest or East on this.

Senator ADAMS. That is my understanding. But I just want to tell you we have got it.

Dr. GOODWIN. What I am saying is, because of the rapidity with which the crack epidemic hit us, the preparations for examining the spread of the ice epidemic have been much faster. And indeed, we have gathered information at a faster rate than before.

MEDICATIONS DEVELOPMENT

Now, the question about treatment. The medication development program that NIDA is running, which has expanded this year by about 20 percent, in our view is an absolute linchpin of what we can do for crack or related addictions, such as methamphetamine.

Senator ADAMS. Do you have sufficient money in this? It seems to me that this epidemic is running faster than we are catching it, and that if we do not catch it, it will overwhelm us.

Dr. GOODWIN. Yes; two things about the money: one is the total amount and the other is the stability of the amount over many years. In other words, we feel that our ability to develop medications, which is a very focused activity that involves critical animal studies and the development of animal models for addiction, involves critical early clinical trials.

This is much analogous to the medication development program that the National Cancer Institute ran for many years, and very effectively since 21 of the 23 drugs that are used as anticancer agents came from NCI's own medication development program.

Now, in terms of the amount of money, if you are asking my professional judgment and if you are asking me over a 5-year period, we could use more. The question about how much we could use in this fiscal year, we think we are close to what we can manage: given the startup costs and the fact that we have just started this program over the last 18 months.

If you are asking me to project over the next 5 years, we feel that this is an area that is going to have to expand considerably above the overall expansion in the budget. We anticipate that the growth rate in the medication development program will have to be somewhere in the range of 20 to 25 percent a year.

In my professional judgment, if we do not have additional funds to do that, we will be faced with the very difficult task of taking it out of other research areas that are equally important, such as epidemiology or treatment.

In regard to the crank epidemic, the fact that there are similarities in the brain mechanisms for addiction to crack cocaine and the fact we now have four different medications that are in development, that have gone through their animal testing and are now in clinical trials, gives me encouragement.

Now, the question of how to get those people into treatment—how to access the public system, and how to get enough slots in the right places needs to be pursued. The ADAMHA budget in treatment has doubled in the last 2 years.

TREATMENT FACILITIES IMPROVEMENT

Senator ADAMS. Doctor, I will say this—and I want to commend the chairman for his emphasis on the rural areas, and while you were gone I have followed up with the problems that are in the rural areas with regard to particular designer drugs, as well as to importation.

Doctor, there are two ways that we can do this. I know you are going to be holding hearings in Iowa. I hope we will have an opportunity to hold hearings in the State of Washington. I mentioned we had gone from 4 to 93 lab busts from 1984 to 1988.

One is that public attention be directed, which we do by going to the prosecutors and the other groups. The second is, I want to be certain that the departments are doing this on a multiethnic, multilingual basis. We have a series of pipelines that come into the Pacific Northwest. One comes up through Vancouver out of the golden triangle and down; and the other comes up from Mexico, on up through various parts of the State, aiming at the market there and then for distribution elsewhere.

We need to be certain that we have a program that proceeds on a multilingual basis and with that community. I know that we are all prepared to go in there and work with those community leaders, which you already have started to do. But they just want to be certain that the Government means it, that it is not just talk, that you may have a drug in time, that you will tell them what these things do, and that you will indicate the size of the problem, because they are prepared to help break the chain, but they do not know what to do with their children or their younger people or those that are already addicted, doctor.

It is just a tragic, tragic thing, because crack comes on them so fast. I do not know anything about this ice or crank, but I understand it is going to come on them just as fast, and it is overwhelming those smaller communities.

I have asked Mr. Bennett to designate that as an area. He went in his own good judgment to other areas. But I think our treatment facilities need to be improved there.

Dr. GOODWIN. One of the problems you are outlining is the speed with which new epidemics appear, and so our priorities have to be reshuffled. Now, your State has about $22 million in the ADMS block grant program, which includes a substantial increase for drug abuse. We would be happy to provide special technical assistance, to come to Washington and help the State authorities look at how they are spending that $22 million in Federal block grant funds and see if there are more effective ways to utilize these funds.

Senator **Adams**. Doctor, I would appreciate that very much. I hope you will work with our office and do it, because we will press forward with that program.

Dr. Mason, I did not mean to ignore you, but I have a particular problem that I am dealing with here, and this happened to be in his area.

Thank you, Mr. Chairman. It is an excellent panel.

Senator **Harkin**. Thank you very much.

Senator **Specter**. Mr. Chairman, if I might, if you would yield for one moment, I would like to associate myself with your remarks and Senator Adams' comments on the need to increase health services in rural areas. I know from my own experience in Pennsylvania that the same situation prevails there.

FARM SAFETY

Senator **Harkin**. I appreciate that. I would like to now turn to the Centers for Disease Control, Dr. Dowdle. Dr. Dowdle, let me just say one of the reasons I was so excited about taking over the chairmanship of this particular subcommittee was because of my interest in rural health, rural health matters, and especially as it pertains to those that actually farm.

I come from a small rural community in Iowa. I know that over the years I have become increasing alarmed at the number of accidents and fatalities, injuries, other health-related matters, and how they are affecting farmers and farm families.

I was alarmed to learn early last year that, even though farmers only comprise about 2 percent of the entire work force, that farmers are the second highest in the United States in terms of occupational-related fatalities; that they are the second highest in the number of respiratory ailments; and the highest in the Nation in terms of skin disorders. Yet they only comprise 2 percent of the entire work force.

Having learned that, along with my colleagues—I can speak for Senator Specter, too, because he led in that area; he has a rural background, a very small town, a rural background—and the other Senators on this committee, last year we put in $11.8 million to begin a new initiative that had not been done before relating only to farm safety and farm health matters, to try to get better data on why these accidents were happening, why the fatality rate is so high, respiratory ailments, skin disorders, why they are so high, and what we can do about it.

I would like you to review for me, if you would, what you have done with that $11.8 million, where you are focusing that attention, and what you see for the year ahead.

Dr. **Dowdle**. Thank you very much, Mr. Chairman, and thank you for your interest in farm safety and health, clearly a major problem. I should like to add that the figures you quoted for farm injuries and fatalities apply to adults, that is those individuals over the age of 16. The realities of farming, as you well know, are that many children work on the farms as well. So when we talk about 700 deaths, we are also talking about another 300 deaths from children alone.

Senator HARKIN. I understand. 300, this is below the age of 16?

Dr. DOWDLE. Yes; below the age of 16.

Senator HARKIN. 300 below the age of 16 children are killed each year in farm-related accidents?

Dr. DOWDLE. Yes, sir.

Senator HARKIN. So that is over and above the 700?

Dr. DOWDLE. Yes, sir; so it is far out of proportion of the number of individuals.

Senator HARKIN. Very far. Well, go ahead, take it.

I just wonder, why is that? Any thoughts on that? But go ahead and tell me what you have done with the money?

Dr. DOWDLE. Well, of course those are the real challenges. First, we have already made arrangements for a Surgeon General's conference on rural safety and health, which will be held later on this year, in the early fall.

Considerable effort is being put on surveillance through a farm family health and hazards survey, for example. This survey will find out really what is happening and what is going on, to determine actual risks among farm populations.

There will be three to five cooperative agreements with State health departments on that survey. We are also proposing that 30 to 50 nurses, who have occupational health experience preferably, be assigned to rural communities through State health departments. Activities would include visiting the farms, actually reporting on agricultural-related disease and injuries, and providing instruction on ways to prevent farm-related injuries and illnesses.

In research, the Centers for Agricultural Research would be established in two or three medical centers within the area. These would conduct applied research on farm safety and health. Actually, these would be designed to look carefully at the risk and what might be done to intervene.

Lung disease research will be carried on by NIOSH and the very expert staff available there. The farm health promotion program will support cooperative agreements with 15 land grant universities to expand their cooperative extension services, which many rural residents are familiar with, and to provide information to promote health and prevent farm-related disease and injuries.

Finally, in cancer screening of farmers there would be three cancer control demonstration projects.

Farm safety and health education training will take place in the Educational Resource Centers. There would be about five, located throughout the country.

CANCER SCREENING OF FARMERS

Senator HARKIN. May I go back to the cancer?

Dr. DOWDLE. Yes, sir; I am sorry.

Senator HARKIN. Let me just stop you on the cancer screening aspect there. That is one that I have interest in. Again, I do not think it is anecdotal, but the more I talk to farm families both in Iowa and around the country, the more they are telling me how their friends and neighbors have cancer, or in their own families.

In speaking to some health professionals in Iowa, I was commenting on this and the high morbidity rate of farmers who do have cancer or farm family members who have cancer. Their response was that one of the reasons is that farmers do not come in for checkups that much. They live way out in rural areas, it is a long distance in. They may have a small rural hospital that really cannot do that kind of testing.

So by the time the cancer is detected, they are too far along for any effective treatment.

So is the cancer screening a pilot program or something to go out and see how you can get out to farmers, to get them screened early on? Is that the thrust of this?

Dr. DOWDLE. Yes, sir; there will be three demonstration projects to really determine, first, how it can be done best, and then to begin to use that system to intervene.

We also have a major program at CDC on breast and cervical cancer, and of course that expertise would be brought to bear as well.

Senator HARKIN. OK, that is what it is for. All right, good. Thank you.

Go ahead. I am sorry.

Dr. DOWDLE. We are pleased to be this far along. We will have those projects in place by the end of this fiscal year, up and running.

Senator HARKIN. Again, these are all good first steps. What more needs to be done? What do you think we ought to be looking at next year?

Dr. DOWDLE. Well, I think, as you pointed out, Senator, this is a first step, and clearly one sees this as a beginning. As to what could be done next year, I think we have to look very carefully at what appears to be the most efficient in terms of how do we get the biggest bang for our buck and what will be most effective in addressing this major and unexcusable toll among farm families.

I think that is yet to be determined. But clearly surveillance and intervention efforts would be the highest priority.

Senator HARKIN. As I understand it, in the budget request it is just continued at that base level?

Dr. DOWDLE. Yes, sir.

Dr. GOODWIN. Senator Harkin, I might add that in the urban areas the biggest single contributing factor to accidents is substance abuse. If you look at the large city data in emergency rooms, people coming into shock trauma units, some 50 to 60 percent have intoxicating levels of drugs or alcohol.

The NIDA is now expanding its surveys to include the rural areas and see if the contribution of drugs and alcohol to accidents in the rural setting is at the same level as it is in the urban areas.

BIRTH DEFECTS

Senator HARKIN. Let me ask one other thing. It is my understanding that birth defects are the leading cause of infant mortality in rural States, and that there are studies that have shown an association between those birth defects and chemicals used in farming.

Is that so, and what is CDC doing to address this problem, and what more needs to be done?

Dr. DOWDLE. We have a major birth defects study at CDC. It is very difficult, though, to actually associate birth defects with specific chemicals. That is a major problem, and I think that right at the moment, other than some well-known chemicals, we cannot say whether those that are specifically used on the farms are those which are responsible for the birth defects.

Senator HARKIN. But some you can say?

Dr. DOWDLE. Yes, sir; that are well known.

Senator HARKIN. I should ask about hepatitis B, but that is Senator Bumpers. [Laughter.]

Senator BUMPERS. Thank you for your deferential treatment.

BREAST AND CERVICAL CANCER

Senator HARKIN. One other one that I wanted to cover with you here and you just mentioned briefly. Last year this committee provided $5 million to begin a new initiative to reduce the incidence of breast and cervical cancer. Again, in this year alone 142,000 new cases of breast cancer will occur, and an estimated 43,000 women will die from this disease. This hits me particularly hard because I lost both of my sisters to breast cancer.

Cervical cancer results in approximately 6,000 deaths a year. As you indicated, the technology and knowledge exist to substantially reduce these unnecessary deaths. Again, what is CDC doing to implement this program that we initiated last year at the $5 million level?

Dr. DOWDLE. During this year we will establish programs in three to five States which these programs will involve very extensive collaborative arrangements with State health departments.

To make sure that we serve those women who are at risk, we will provide information to health providers, will help States establish screening programs and quality assurance systems, and will support general public education programs.

Senator HARKIN. What would it take in terms of money to have available to every woman in America? At what age should women start having mammographies?

Dr. DOWDLE. Well, by age 40.

Senator HARKIN. Thirties, some say.

What would it take in terms of money to try to get every woman in America to start at an early age having mammographies, say in the late thirties?

Dr. DOWDLE. We could give those figures to you, sir.

Senator HARKIN. I would like to know what it would come to.

[The information follows:]

MAMMOGRAPHY

Until the past 2 years, data from the major trials of mammography demonstrated clearly increased survival only in women aged 50 and older at the time of diagnosis. Longer follow-up of the screened women has now demonstrated that there is an increased survival of women who were screened in the 40–50 year age group. No survival advantage has yet been demonstrated in younger women. All major organizations now agree on screening recommendations for asymptomatic women. Mammograms are recommended every-other-year for ages 40–49 and annually at age 50 and older. The baseline mammogram at age 35 previously recommended by the American Cancer Society is no longer part of the recommendation.

CDC estimates that $6 to $7 million per State is needed to provide screening to U.S. women aged 40 and over. This estimated amount represents funding needed to screen the approximately 15 percent of U.S. women that are uninsured, and assumes a cost of $50 per mammogram. The estimated funding includes follow-up activities; assuring the highest quality of the screening test; and provisions for public and professional education, necessary components for a screening program that would benefit both insured and uninsured women.

Senator HARKIN. And what else might have to be done? Obviously, you would have to have outreach programs, educational programs along with it, why it would be important for them to do that.

Dr. DOWDLE. Yes.

Senator HARKIN. But it seems to me that there is not enough of that outreach out there to educate people, women, on the necessity of getting that kind of early screening and, as you say, keep them in the system for the continuous screening.

That is basically all I had. Senator Specter?

LEAD POISONING PREVENTION

Senator SPECTER. Thank you, Mr. Chairman. Just a question or two.

Dr. Dowdle, we added some funding last year for lead poisoning prevention, approximately $4 million, and that has been a recurrent problem that I have noted in Philadelphia since my days as district attorney a long time ago. I see statistically that there are more than 170,000 children in Philadelphia and more than 71,000 in Pittsburgh between the ages of 6 months and 5 years who live in pre-1950 housing.

My question is, how effective will that grant and the program pursuant to that grant be in addressing the problem?

Dr. DOWDLE. Well, there is no question that this is an important problem. There is also no question Philadelphia probably has the highest number of houses that have lead-based paint.

Senator SPECTER. How do you account for Philadelphia having that leadership distinction?

Dr. DOWDLE. I do not know that I can account for that.

Dr. MASON. I think, and I am not certain that this is true, but a lot of battleship paint, gray paint, was sold at very reasonable costs right after World War II, and it had a high lead content and was applied in a lot of the inner city homes.

But I cannot say that specifically for Philadelphia, but since it is a port it is very likely that that may be one of the problems.

Senator SPECTER. So that establishes the Federal legal responsibility here. [Laughter.]

Dr. Mason. I think at that time probably there was not the general recognition in the United States of the threat or what low levels could contribute to significant problems in kids.

Reports that have come out in the last few weeks in the New England Journal of Medicine and the Journal of the American Medical Association show definite IQ patterns associated with very low levels, levels that at one time were thought to be nontoxic.

Dr. Dowdle. To answer your question, though, sir, this grant program will pay for screening to detect blood levels among the children. What it does not pay for, of course, is removal of the paint or cleanup of the soil, and there we have been working with HUD to see what can be done once high lead levels are detected in children.

Senator Specter. Have there been any findings so far as to the impact on the children with access to this lead paint?

Dr. Dowdle. As far as the lead that was in children in Philadelphia? Yes, sir; we do know that Philadelphia is screening and providing followup with their own funds. I do not have those reports yet.

Senator Specter. Have there been any findings yet?

Dr. Dowdle. Yes; there have. We could give those to you if you wish.

[The information follows:]

The data from Philadelphia is preliminary and the city is unable to provide detailed information at the present time. We will provide you the data as soon as possible.

Senator Specter. You do not have any idea at this point as to what those findings are?

Dr. Dowdle. I do not have any idea, no, sir.

Senator Specter. Thank you very much, Dr. Dowdle.

Thank you, Mr. Chairman.

Senator Harkin. Thank you, Senator Specter.

Senator Bumpers.

NATIONAL HEALTH SERVICE CORPS [NHSC]

Senator Bumpers. Thank you, Mr. Chairman.

Dr. Harmon, I want to ask you about this $55 million increase in recruitment for the National Health Service Corps. First of all, I want to congratulate whoever is doing this. I thought it was barbaric to discontinue that program when we have so many areas where these doctors could be used.

But let me start off by asking first, how many medical scholarships do you think you can give with this money?

Dr. Harmon. Well, it is a little difficult to say right now because the funds would probably be split between scholarships and loan repayment grants, working with the States. So there would hopefully be some flexibility if the authorization so indicates.

Senator Bumpers. How many did you recruit last year into this program?

Dr. Harmon. Recruitment and placement, I do not have that figure in front of me. I would have to get that for you, Senator.

[The information follows:]

OBLIGORS

Last year we recruited 42 scholarship obligors, 112 Federal loan repayment obligors, 74 State loan repayment obligors, and approximately 400 volunteers of whom over 200 are serving in community and migrant health centers as freestanding NHSC sites.

NHSC DOCTORS

Senator BUMPERS. Well, it would probably have been less than 10, would it not? Would it have been more than 10?

Dr. HARMON. Well, scholarships in 1989 were 42.

Senator BUMPERS. Forty-two.

Dr. HARMON. In fiscal year 1989.

Senator BUMPERS. How many National Health Service Corps doctors do we have that are out in practice and doing their repayment? Do you know the answer to that?

Dr. HARMON. The obligated field strength as of January 1, 1990, is just over 1,300.

Senator BUMPERS. In practice now?

Dr. HARMON. Yes; this level is about 1,200 below the 2,500 level we consider a reasonable goal.

Senator BUMPERS. Get up to how many?

Dr. HARMON. Ultimately, we would like to achieve an obligated field strength of 2,500.

Senator BUMPERS. Well, I am going to do my best to see that you get full funding for that. That just happens to be a program I strongly believe in, and the reason I do is because we have very deep-seated pockets of poverty in the delta region of Arkansas, and if it were not for our National Health Service Corps doctors we would have no health care.

I was amazed President Reagan tried to torpedo that program every time he got a chance. It is a badly needed program.

I commend you or whoever is responsible for rejuvenating it.

Dr. HARMON. I am a big supporter of the scholarship program. This would especially be targeted for minority students and for our neediest areas. The scholarship recipients tend to go to the neediest areas.

The loan repayment, it is a little harder to get those individuals to go to the neediest areas, because there is an element of voluntarism in that.

Senator BUMPERS. Do you have any idea how many areas we have in the country that need these doctors? What is the need? Not the area, but what would you estimate to be the need for these doctors in the country?

Can you give me just a ballpark guess?

Dr. HARMON. Well, our estimate is that we ultimately need 4,200 doctors if we were fully covering the health manpower shortage areas around the country.

Senator BUMPERS. So we would have to recruit at least 750 a year to maintain that kind of a Corps, would we not, because they graduate out? Is it year for year? They give a year's service for each year of medical school?

Dr. HARMON. That is correct.

Senator BUMPERS. And so they graduate out as they go along, do they not?

Dr. Harmon. That is right.

The new provision, if they do not go to the neediest areas, many of which are rural, they would actually be required to do, if we get the authorization, a year and a half for each year of scholarship receipt.

Dr. Mason. Senator Bumpers, we are also interested in keeping a lot of these Health Service Corps doctors so that they set up practice permanently, and so there is also money in the budget to——

Senator Bumpers. Supplement their income?

Dr. Mason [continuing]. Provide supplementation at the community.

Senator Bumpers. Have you had any luck in that, Dr. Mason?

Dr. Mason. Well, it is just going into effect. But we feel that if the salary level and other conditions can be improved, that more of these people will stay, because ultimately we would like to have people that set up their homes and reside in the area and become part of the community.

So we want to get more Corps physicians into the program and then to do things that will keep them in the delta if it is at all possible.

Senator Bumpers. It is the toughest thing in the world to do. When I was Governor I concentrated intently on trying to get students out of medical school who would agree to go back to those areas. We would give them a $5,000 a year stipend, we would supplement their incomes once they went back.

We did everything. And to be quite frank, the program was only marginally successful, despite all of my best efforts and the money we spent on it.

Dr. Mason. That is why we would like to target, both in professional training as well as in scholarships and loans, minority people who will be perhaps more inclined to stay there, by targeting who goes to medical school and nursing school and these other schools, because this may make a difference.

Senator Bumpers. I think that is absolutely right, Dr. Mason.

Dr. Harmon. We would hope that reimbursement reform down the road, giving more reimbursement to rural areas, would help to be an incentive to physicians to locate and stay there.

HOME HEALTH CARE

Senator Bumpers. Dr. Harmon, funding for grants to States for AIDS home health care has been zeroed out. I have always been interested in home health care for the elderly, because I thought the amount of money we could spend to keep seniors out of a nursing home was very cost effective.

But I am interested in home health care from another standpoint, and that is for AIDS patients. They tell me 25 percent of the hospital beds in New York are occupied by AIDS patients.

A lot of those people can at least postpone hospitalization with fairly intensive home health care. Then all of a sudden I look here and I see the $19 million we spent this year, in 1990, is being zeroed out.

Why is that?

Dr. **Harmon**. Well, it is a difficult decision. Some of that home care can be picked up by Medicaid. These are pilot projects, and it is the kind of thing that is difficult to sustain in the long term with these kinds of grants.

We would hope eventually that private insurance and Medicaid would help pick up some of those services.

Senator **Bumpers**. That is true in the case of Medicare and Medicaid, but it is not true in an awful lot of young AIDS patients, who are going through a very expensive ordeal, and so many of those do not qualify for Medicaid.

Dr. **Harmon**. That is true.

We are also expanding some of the other areas of community health center funding in the AIDS area, and also are expanding some areas in our education and treatment centers to try to provide some alternatives to that.

HIV/AIDS REIMBURSEMENT

Senator **Bumpers**. One of the other things along that same line, I see you are zipping HIV/AIDS drug reimbursement this year, $29,606,000. This is also to provide AZT treatments, essentially, for AIDS patients who do not qualify for Medicare or Medicaid.

Why are we zipping that out? That is a very expensive treatment process, is it not?

Dr. **Harmon**. Well, it is another difficult decision. In this case, fortunately, the dosage of AZT has come down, so it is lowering the cost per year for treatment. Hopefully, these patients taking AZT will be able to continue better in their employment and private insurance would help pay for this.

More and more States are now paying for Medicaid, and hopefully they are gradually increasing their eligibility for more patients. And while they cover the drug AZT, it is a difficult decision that we did not come by lightly.

Dr. **Mason**. Senator Bumpers, we in the administration are gravely concerned about beginning a categorical program relating to AIDS. We feel that perhaps the AIDS epidemic has demonstrated some underlying problems with our health care system.

I think we were aware of that. It did not take AIDS to bring us face to face with that problem. But AIDS certainly has magnified and helped to decompensate the health care system, and that is why Secretary Sullivan has asked Under Secretary Horner to look at this very problem, this 37 million who are out there that are significantly underinsured or have no insurance, how do we bring that group into the system?

We would rather attack the whole problem than begin categorical programs for patients with AIDS. We understand the magnitude of the needs, the severity of the needs, but we feel we ought to solve these in systems that exist for all and not identifying just one cause of suffering and death as a means.

Senator **Bumpers**. Dr. Mason, I understand what you are saying. But I think that you are leaving a void. I think that AIDS, first of all, it is a rather unique condition. I am not suggesting that AIDS patients receive more money and undue consideration, for example, as compared to cancer patients or emphysema or anybody else.

But you are recommending AZT intervention very early, at the earliest possible time, low dosage, as Dr. Harmon has pointed out. And yet this medication is very expensive.

If a young guy out there who has just discovered he is HIV-positive, if he is making $20,000 a year and he is strapped to keep his apartment rent paid and his car payments made so he can get to and from work, and he is certainly not eligible for Medicaid or Medicare, and yet you are saying to him early intervention is the key to his problem. And he is just saying: I just do not happen to have any money to buy AZT.

That is what this $29 million is designed to do, and we are zeroing it.

Go ahead.

Dr. MASON. For the very reason that I described, that we are reluctant to bring up a categorical program relating to the need.

Senator BUMPERS. People are dying, Dr. Mason. You cannot stand on the philosophical premise when people need this to stay alive.

Dr. MASON. They are dying of other diseases as well.

Senator BUMPERS. I know it, and tell me how this affects anybody else?

Dr. MASON. We have young people who have diabetes, other diseases, cancer, and we do not identify them as a categorical group to provide treatment. We bring them into the system, the public-private system.

It is just our feeling that in the long run we will help more Americans by moving right down the line of providing a comprehensive health care system. The Public Health Service in the context of AIDS is responsible for research and prevention. We never have been given a major responsibility for health care financing.

Senator BUMPERS. Dr. Mason, let me make a distinction for you. If a young man has cancer and he has no health care coverage, the hospitals of my State say that their free care runs anywhere from 25 to 50 percent of their total cost, and that one of the reasons is because of these long-term care patients, principally cancer, who have no insurance. They do not turn them down for hospital care.

In this case we are not talking about turning somebody down for hospital care. We are talking about providing money so they can take a medicine every day, a medicine that prolongs life and postpones hospitalization.

We are not asking for these people to be hospitalized. Is that a distinction or a distinction without a difference?

Dr. MASON. I well understand where you are coming from, and I think here in this area we feel that we would rather solve this comprehensively. Outpatient drugs you are talking about—and there are others that go without outpatient drugs.

I think we need to solve this comprehensively as a system here in this country, and it has been a decision that the Public Health Service will not be responsible for the treatment system.

Senator BUMPERS. Mr. Chairman, I just have one other area and that is CDC, Dr. Dowdle.

SECOND DOSE MEASLES VACCINE

Two or three things. No. 1, second dose of measles, which your own advisory committee tells you is necessary. We had 14,000 plus cases of measles last year, up from 3,000 plus in 1988. Your advisory committee and all the pediatricians in this country are saying, we have got to have a second dose of measles.

That, my staff says, is going to cost about $51 million a year total, unless Merck dramatically reduces the cost of vaccines. And incidentally, I applaud them because they apparently are going to cut their cost by about 12 percent to you.

But you are talking about $51 million. If you put up one-half, the States are so strapped—it's not clear they'll be able to put up their half.

So we have got to do something about the second dose of measles if we are really serious about keeping this 14,000 plus outbreak from occurring again, to give the second dose, either at entry to elementary school, first grade, or at college entry.

No. 2, give me an update on the pertussis clinical research that you are proposing to do with the roughly $6 million we got you last year?

Third, give me some idea of how you think we are doing on hepatitis B?

Dr. **Dowdle**. Let me simply say that you are correct, sir, on the cost of the second dose of measles vaccine. That would be both for entry into elementary school as well as entry into college. For both these cohorts, $51 million at current vaccine prices would actually include the entire cost of the program.

If we assume that the States would do one-half of that, we are talking about $26 million. However, that cost may be somewhat higher in the beginning since many States have not budgeted for the second dose of measles vaccine.

We are in the midst of working with Merck right now and hopefully we will get a reduction in vaccine price. But 12 percent does not reduce it as far as we would like to see it.

Senator **Bumpers**. Not enough to solve this problem.

Dr. **Dowdle**. No, sir; it is not.

Let me speak to hepatitis B——

Senator **Bumpers**. Well, let me just say I think we are going to put the money in here. I think that the chairman would agree with me that this measles problem is severe enough that we have got to put the money in there for the second shot. We have got to get cracking on that.

Now, whether the States will come up with their half or not, I do not know. My guess is we are not going to put $51 million in here, and we may not put $26 million in here. If we can get something resolved with Merck between now and the time this committee marks this bill up, we will take that into consideration, too.

Go ahead now.

INCIDENCE OF MEASLES

Senator **Harkin**. If I might, Senator Bumpers, interrupt right there.

Could you supply for us, Dr. Dowdle, could you supply for us the increase? Do you know off the top of your head how much the increase has been in measles in the last year or two, how much it has increased, the number of reported cases of childhood measles?

Dr. Dowdle. Well, we have had provisionally reported approximately 14,000 cases, but actually it is closer to 17,000 cases that toward the end of the year have not been firmed up. We have also had reports of 43 deaths, which are unconfirmed at the moment, in nearly 17,000 cases.

Senator Harkin. Of how many total cases? What I want to get into is, do you have any track on the number of increased cases in measles in the last 2 or 3 years?

Senator Bumpers. Well, let me give you the statistics, Mr. Chairman. I have got it from CDC.

Senator Harkin. What is it?

Senator Bumpers. In 1987 3,365; in 1988 3,396, or a slight decline; and in 1989 14,714. But that is provisional data through December 16.

He is saying upgraded data shows 17,000 cases, or roughly an increase of 400 percent in 1989.

Senator Harkin. Do you have any data to indicate the number of long-term effects of cases—what I am trying to think of is long-term——

Senator Bumpers. Symptoms?

Senator Harkin. Symptoms, or long-term health problems?

Senator Bumpers. Like the rubella syndrome?

Senator Harkin. Like rubella, or like some measles lead to deafness, some lead to partial paralysis. In other words, things that affect that person, that affect that person for the rest of their life.

Dr. Dowdle. No, sir; these are acute cases and, of course, other than the immediate illness, there is also the issue of the 43 deaths.

Senator Bumpers. Mr. Chairman, in 1974 8 percent of all people institutionalized in this country were there because of measles, mumps, or rubella syndrome, those childhood diseases.

Senator Harkin. What I want to get a handle on is how many of these cases, if we have any data at all, show whether or not there was deafness as a result, partial paralysis, blindness, other types of chronic disabilities that will linger for the rest of their lives, because that gives us an idea of what it is truly going to cost the society down the road compared to the $51 million that we need for the second shot.

Dr. Dowdle. Of course, measles does affect the brain in a certain number of cases, but we do not have any evidence at the moment as to how many of these complications may occur as a result of measles cases reported during 1989. This generally occurs later in life, so we cannot give you that data at the present time.

The 17,000 measles cases are acute cases.

HEPATITIS B

Do you want me to answer the hepatitis B question?

Senator Harkin. No; are you through, Senator Bumpers?

Senator Bumpers. Oh, we were just getting hepatitis B.

Dr. Dowdle. Yes, sir.

Senator BUMPERS. Go ahead.

Dr. DOWDLE. The hepatitis B vaccine program will be underway this year. Of the $10 million that was provided to us, $7 million will be given to State programs to help them screen and provide vaccine and immunoglobulin to affected mothers.

Senator BUMPERS. Dr. Dowdle, in the case of hepatitis B it is my understanding that about 16 women per 1,000 are hepatitis B carriers. Of course, you intervene at birth of the child and it is 90 percent effective; is that a fair statement?

Dr. DOWDLE. Yes, sir.

Senator BUMPERS. My question is, In a perfect world and assuming that the Government was not bankrupt and you had all the money you needed to really wipe out hepatitis B, how much money would it take?

Dr. DOWDLE. Well, we have projected 1.8 million pregnant women who would be served in the public sector.

Senator BUMPERS. 1.8 million?

Dr. DOWDLE. 1.8 million, yes, sir.

With $10 million we currently have now enough to cover about 56 percent of the women. Then with another $4 million or so, one could get essentially most of those women in the public sector.

But we have to keep in mind that this is an extremely difficult group to get.

Senator BUMPERS. I understand.

Dr. DOWDLE. Many of these women do not have the prenatal care that one might wish.

Senator BUMPERS. The private sector is doing a pretty good job of this, are they not?

Dr. DOWDLE. Yes, sir; they are, the pediatricians.

Senator BUMPERS. The pediatricians are screening all the babies.

Dr. DOWDLE. They are really doing well.

Senator BUMPERS. So it is in the public sector where the problem lies.

Dr. DOWDLE. Yes, sir.

Senator BUMPERS. That is fine.

IMMUNIZATION

Mr. Chairman, the last thing I will ask Dr. Dowdle to discuss is the $6 million provided last year for pertussis research. We went into this at this same hearing last year.

A lot of people think that we are not doing all that we ought to do to eliminate the profound problems with pertussis vaccines. Last year, in that connection, I asked and this committee gave you $6 million to start clinical trials on pertussis vaccines.

They are not really trials as I understand it. They are to coordinate all of these pertussis vaccines that have not yet been approved, but which show promise.

Now, where are you on that?

Dr. DOWDLE. The reason I asked that we put that last, sir, is that those funds were given to the National Vaccine Program Office.

Dr. Mason?

PERTUSSIS VACCINE

Dr. **Mason**. We cannot hold Dr. Dowdle responsible for those. I am the Director of the National Vaccine Program, and that is in the Office of the Assistant Secretary for Health.

You are absolutely right, we need a better pertussis vaccine, and certainly the acellular vaccines appear to be very, very promising. As you know, we invested a considerable amount of money in the Swedish trial and did not get all of the information that we hoped we would get from that.

The money is now being used to support clinical field trials and research activities related to both the development and licensing of improved pertussis vaccines. All of these under consideration at the present time are acellular. Unfortunately, most of these field trials cannot be carried out in the United States because we have too high a vaccination rate.

Senator **Bumpers**. I understand.

Dr. **Mason**. We are not complaining about that. That is what we want to maintain. But we are looking at other populations and trying to move as rapidly as possible—that is NIH, CDC, FDA—so that those studies that are needed can be done, so that we can license as rapidly as possible a product for use here in the United States.

Senator **Bumpers**. That is actually in OASH, is it not?

Dr. **Mason**. That is right.

Senator **Bumpers**. Dr. Mason, is the Japanese vaccine one of those that you are testing or not?

Dr. **Mason**. The Swedish field trials were carried out on a Japanese acellular vaccine. Unfortunately, the Japanese had not used it in—it was used only down to age 2, and of course we know in the United States, if we are really going to prevent pertussis and the complications, you have got to have a vaccine that can be used soon after birth.

So we are looking back at what other trials might be crafted so that we can look at an earlier age. I can get for the record or for you in writing detailed progress reports on how that money is being used, because we sense your urgency, and our urgency as well, that as rapidly as possible we have a substitute for the current vaccine, although we do not feel today that it is as bad as many people feel it is. But it is the perception.

I am glad my grandchildren have all had the current cellular pertussis vaccine, and I think the risks have been overstated. But for a perception reason, if not for others, we ought to do better.

[The information follows:]

Pertussis Vaccine

In fiscal year 1990, Congress earmarked $4.421 million and 7 FTE's of the NVP budget for CDC, FDA and NIH to conduct research activities that would lead to the licensure of an improved (acellular) pertussis vaccine in the United States.

The National Vaccine Program (NVP) is allocating $2,948,000 for the National Institute of Allergy and Infectious Diseases (NIAID) at NIH to carry out pertussis vaccine trial activities to determine the efficacy of candidate acellular pertussis vaccines compared to whole-cell vaccines. The level of effort of six Vaccine Evaluation Units (VEU's) supported by NIAID is being increased to fund multicenter phase I and phase II clinical trials of candidate acellular vaccines. The results of these trials will be helpful for selection of the most appropriate vaccine(s) for the full-scale pertussis vaccine efficacy trial(s), which will probably not begin until fiscal year 1991. The VEU studies will begin in March 1990.

Other specific activities associated with the field trial(s) include: purchase of whole-cell vaccine to be used as control vaccine in the phase I/II multicenter trials; contract(s) for the first part (study design and protocol preparation) of the full-scale (phase III) clinical field trial(s); additional pre-field trial clinical studies; operational support for NIAID staff in carrying out duties required by the field trial; and purchase whole-cell vaccine for the comparison arm of the efficacy trial(s). The funds will also cover activities for central serology laboratory testing, a vaccine distribution center and data management.

The NVP is also allocating three FTE's and $393,000 to CDC; three FTE's and $491,000 to FDA and one FTE for the pertussis efficacy trial and $589,000 to NIH to carry out additional basic and applied research to elucidate mechanisms of pathogenesis, identify candidate vaccine antigens, provide improved diagnostic methods, and determine immunity to pertussis.

MEASLES VACCINATION

Senator **Bumpers**. Has there been a recommendation, Dr. Dowdle, that children be immunized with their first shot for measles at 12 months of age?

Dr. **Dowdle**. There is a recommendation for those inner city areas where there tends to be an endemic problem, and actually it can be anywhere down to 9 months, 9 months to 12 months.

Senator **Bumpers**. What do they do in the private sector? What do they do in the private sector, 18 months?

Dr. **Dowdle**. Yes, sir; it is after 15 months.

Senator **Bumpers**. OK. I have a few questions that I may wish to submit in writing, Mr. Chairman.

I thank you for the time. And gentlemen, I thank you very much for your help this morning.

RURAL DRUG TREATMENT

Senator **Harkin**. Thank you.

We are going to now move to ADAMHA and then to HRSA. I have a few questions basically for Dr. Goodwin, and basically it has to do with substance abuse. Again, in rural States we see an increasing number of substance abusers. In my own State of Iowa, it has been estimated about 180,000.

The economic impact of this is tremendous. We tend to think about the drug problem in our larger cities and we focus on that, but in our smaller towns and communities where it is not a big problem, but it is a growing problem, and where maybe just a little bit of money, a little bit of help, might be able to stem that increase.

So my question basically is, what are you doing, again, to ensure that rural States and smaller cities are not left out when it comes to treatment programs?

Dr. **Goodwin**. That is a very important question, and it is somewhat complicated. As you know, there are various urban-weighted formulas built into the block grants because of the perception at the time that the drug abuse epidemic was primarily urban-driven. This formula limits what can be provided to States.

I think that the complexity of that block grant formula and its impact on the urban-rural distribution, is something that can be adjusted with technical corrections in next year's reauthorization process.

In terms of categorical programs in the treatment area the new Office for Treatment Improvement has programs for underserved populations and these include rural areas as a primary target. The Office for Substance Abuse Prevention, as part of its targeting of underserved populations, has authority for treatment of pregnant and postpartum women and also for rural populations.

The grant announcement that is now being sent out lists rural populations as one of those underserved areas.

From a budgetary standpoint, the overall drug treatment budgets of the agency, particularly looking over the 2-year period, have been substantially increased. In fact, they nearly double over that period of time.

The prevention budget has increased even more dramatically increased. OSAP, for example, over the last 2 years overall has had a fourfold increase in funding, from $55 million to $220 million.

Its pregnant and postpartum women program focus has increased from $4.6 million to $38 million, which is an eightfold increase. So we think that there is enough new money that Congress has provided in the treatment and prevention areas to focus on these underserved populations.

I might point out, by the way, that when Dr. Mason made reference to the overall emphasis of the Public Health Service, it is noteworthy of the $484 million increase in the Public Health Service budget, $200 million of that is in ADAMHA, and most of that is in drugs, and the majority of that in drugs is in treatment and prevention.

PREGNANT WOMEN

Senator HARKIN. You mentioned how much is going for pregnant women and infants. How much was that you mentioned?

Dr. GOODWIN. That has gone up to $38 million.

Dr. HARMON. It is up $4 million?

Dr. GOODWIN. It was $4 million, $4.6 million 2 years ago.

Senator HARKIN. I have to figure this one out, because our book here says that in 1990 an estimate was that there would be 98 new grants. The 1991 estimate is 15 new grants.

Dr. GOODWIN. Those are the number of new projects in fiscal year 1990 and fiscal year 1991—I think it is more meaningful, in terms of program development, to look at 2 years when you have had very large increases in 1 year. The second year continues what we have started.

Senator HARKIN. And they are continuing on?

Dr. GOODWIN. Yes; there are 118 grants continuing in fiscal year 1991. That is why I think the 2-year timeframes for many of these programs are more meaningful.

Senator HARKIN. I am told, Dr. Mason, you have a plane to catch. If you have to leave, go right ahead. I was just going to cover some items with Dr. Goodwin and Dr. Harmon and we will be through. So catch your plane.

Thank you very much for being here.

Dr. Mason: Thank you very much. I apologize for having to leave.

Senator HARKIN. Go right ahead. I understand.

Dr. Goodwin, when you were in my office a year ago we were talking about some of the new research into—and you were the first one who brought it to my attention; I have sort of been following it a little bit since then—in discovering what areas of the brain are affected by drugs.

Some of that work I think is being done through the use of a machine called PET, PET machines?

Dr. GOODWIN. Yes.

Senator HARKIN. Looking for perhaps interceptors or things that will block the effect of those drugs in those portions of the brain. What has happened on that in the last year?

Is there anything new in that area? Can you bring us up to date?

Dr. GOODWIN. Yes; there have been a number of new developments. As I pointed out earlier, the medication development program which is focused on drugs, although it also may apply to alcohol eventually and to some areas of mental illness treatment, is the top priority of the National Institute on Drug Abuse.

What is new basically can be summarized this way. There have been four medications that were developed initially for other purposes, which have now been explored initially in animal studies.

By the way, I might point out that the only down side of this whole story, frankly, is that we have a climate of fear that has been created by some of the animal rights activists, which by focusing on drug abuse research because they feel the public may not understand the importance of brain research in this area as easily as they might in cancer or AIDS.

We have seen a decline in the number of investigators willing to do animal model studies in drug abuse, and therefore we are worried that that link of our medication development program may be weakened.

Senator HARKIN. What type of animals would you be using in this?

Dr. GOODWIN. Well, we have to use a whole variety, and indeed in this case we have to use primates, because we have to model drugs that are close to the behaviors of humans. In other words, if you are going to study a drug to block addiction, you have to have some addicted animal in which to try it, and we do not feel it is ethical to addict human beings in order to study these drugs.

We have a lot of public education responsibility to help the public understand that this is one of the most important and legitimate uses for animals in humane research.

At any rate, with that aside, there are four drugs that have been developed for other uses: one an anticonvulsant, carbamazepine; another an antidepressant called desmethylimipramine; another, a calcium channel blocker; and another, a dopamine blocker which was originally developed for the treatment of schizophrenia.

Each of these drugs has shown considerable promise in the reduction of cocaine craving in small clinical trials, and preceding that, of course, the clue to that was based on the animal studies.

I will give you just one example just so I can illustrate how this develops. The drug carbamazepine, which is an anticonvulsant, was being tested in another system where cocaine was being used in an animal just as an experimental tool. The investigators found that when cocaine was self-administered by the animal there were small convulsions occurring deep in the brain.

They were not the kind that could be measured with a clinical EEG, but they required deep electrode placement to pick up these tiny convulsions in the emotional centers of the brain.

The investigator who did this in our intramural program of the National Institutes of Mental Health, Bob Post, found that the craving for cocaine only occurred when the small convulsion occurred, so the convulsion was correlated with the craving. He then gave an anticonvulsant drug to see if he could knock out that convulsion, and as a result could he also knock out the craving.

He found, at a dose that had no other behavioral effect on the monkey, that indeed the monkey stopped craving cocaine and turned back to his normal food and water.

This was then picked up by a clinician in Minnesota, who was able to show in a small group of patients in an open study that carbamazepine reduced craving dramatically in a group of very seriously addicted addicts.

Both in our Addiction Research Center in Baltimore and through several of our grantees, we are now doing controlled studies.

But similar stories could be told in medications that have come off the shelf for other things. Ultimately, what is most important is what we are learning in the basic science lab about the chemical nature of addiction—these reward systems in the brain which exists in all of us for legitimate purposes short-circuited by drugs in the addict. How is it that we can selectively chemically interact with these, just like antidepressant drugs have been developed to treat depression, severe depressions, in the majority of patients?

In order to get this done it is going to require a sustained commitment, because it is going to require us to bring investigators from other fields of pharmacology into an area that has been a kind of orphan area. It is also going to require us to get the pharmaceutical industry interested in this, because, although ADAMHA can run a medication development program for $50 million or maybe eventually $100 million or more, we cannot do what the pharmaceutical industry can do.

We know that the cost to bring a drug from the laboratory to market in this country, with all of the testing that has to go into it, is now estimated at around $125 million per drug.

So if this is going to really get from promise to true potential in the community, it is going to require private industry cooperation with us. It may be that Congress will have to independently consider issues such as patent extension or giving orphan drug-like protection to drugs to treat addiction.

The numbers of people in need of such treatment would not qualify for orphan drug status. There are too many addicts. But the disincentives for the drug industry are powerful because of a concern about special regulations, concern about the diversion of their product to an addictive use.

So this is an area where Congress is going to have to look carefully at what the obstacles are, and I mentioned several of them.

There is one other development, by the way, which comes out of the treatment of heroin addiction, a drug called Buprenorphine, which is neither a blocker nor a mimicker, but is mixed. It is halfway a mimicker and halfway a blocker of morphine or heroin.

By an accidental observation, which is often how science goes, buprenorphine was found not only to reduce the craving for heroin, but also to reduce the craving for cocaine in people who were taking both drugs.

That is another target for NIDA's medication development program.

Now, some of our research aims to make existing drugs more effective, for example, methadone is fine, except you have to take it every day. We are developing a long-acting, or a depot injection of methadone that will be active for several days or weeks.

All of this, however, is going to require a sustained research effort and, although I answered the question earlier that, of course, as a professional judgment we could use somewhat more money and that even this year, the real point is that we have to be able to sustain growth in this area over 5 or 10 years or it will not happen.

PROTECTION AND ADVOCACY PROGRAM

Senator HARKIN. Thank you. That was a good briefing.

Let me just switch very rapidly here to something totally disconnected with that, an area that I am greatly interested in, the protection and advocacy. The budget requests a 43-percent funding cut for protection and advocacy in fiscal year 1991, down from $14 million to $8 million.

Can you tell me, was this in your original budget request for protection and advocacy?

Dr. GOODWIN. This was part of a long-term plan within the administration for phasing over protection and advocacy to the States, and this fits in with our notions that the situations that relate to protection and advocacy are indeed very different from one State to another, one locality to another.

In some cases the issues relate to people being released from State hospitals. In other cases it deals with people with mental illness who are in the substance abuse treatment center and are ignored, or vice versa.

We felt that, given the expansion of the block grant and particularly given the set-aside, which allows us considerably more leverage than we had before to require States to set up treatment plans to monitor and treatment accountability, that the total effort to make sure that the State and local areas are competent, not just in treatment but in protection and advocacy as well, is probably, in the long run, a better strategy than having a small program run out of Washington.

Now, we also have, by the way, the continuation of the community support program [CSP], the CSP program in NIMH. These CSP projects involve community-based leveraging of the treatment system, helping people access treatment, and, also including protection and advocacy aspects to them in terms of potential abusive treatment or improper hospitalization and so forth.

Finally, I think the creation of the protection and advocacy movement was at a period of time when there was a lot of concern about the coercive use of psychiatric hospitalization. We think that concern is no longer nearly as relevant as it was at the time that the protection and advocacy programs were originally designed.

Senator HARKIN. Well, in fiscal year 1987 protection and advocacy agencies handled 14,000 cases of residents of mental institutions. In fiscal year 1988, protection and advocacy agencies handled 23,000 cases.

Two-thirds of the clients in fiscal year 1988 were living in public mental health hospitals at the time that they contacted the protection and advocacy. As far as the block grant goes, those increases, all the increases you get there are going to drugs anyway.

ADMS BLOCK GRANT PROGRAM

Dr. GOODWIN. No, no; that depends on the formula. This year, in fact—that is a complicated question, as you know. But this year it could play out that actually many of the increases would end up in the mental health, mental illness area.

This is an issue relating to how the block grant formula works, and it is a complicated question. But our analyses indicate that, if the——

Senator HARKIN. Excuse me, doctor. Staff tells me that ADAMHA has requested bill language so that it would all go to drugs.

Dr. GOODWIN. It has requested bill language so that the formula does not alter the administration's intent of the new enhancements, being drugs—by the way, the mentally ill are included in the drug component because of the very large amount of comorbidity.

PROTECTION AND ADVOCACY PROGRAM

If I could go back to your first question, though, and answer it very honestly, based on my own work as a psychiatrist both in the private and public mental health system for many years—and I know a lot of people in those systems, and I think my colleague Dr. Judd at NIMH feels the same way—although clearly this phasing over of programs in protection and advocacy was part of a larger shift of several initiatives to States after careful examination by the administration, we think professionals in the mental health community, at least an important segment of it in terms of government leadership, agree.

In other words, this is not one of those things where we are being told by the administration to just go along with this and that we are fighting all the way. There probably are cases like that, but this is not one of them.

Senator HARKIN. So you think that you can decrease the funding for protection and advocacy by 43 percent?

Dr. GOODWIN. I think that the efforts of the community support program, the efforts in the improvement in the treatment system in the States, and the leverage that we are getting to improve the State programs, yes, I think that we ought to be able to have those programs taken care of increasingly at the State level, using Federal dollars, in the block grant.

Senator HARKIN. Well, I ought to follow up more with this, but how you go from 14,000 to 23,000—I do not know what it was last year. That was fiscal year 1988. I do not know if we have the data for last year. Do you?

Dr. GOODWIN. No; I can get the data for you, and I was just going to offer that Dr. Judd and his staff from the community support program would be happy to come down, and give you and your staff a briefing on this.

Senator HARKIN. It just seems to me that you have got the number of protection and advocacy complaints going up, yet you want to cut it almost in half, because you say it will be subsumed in some other portion.

I do not see the money there in any other part of the budget.

Dr. GOODWIN. Well, the question is how those protection and advocacy type issues would be handled if there were not a protection and advocacy program out of NIMH. I would suggest that perhaps we could get into a more thoughtful discussion of that if we could bring Dr. Judd and his people down.

COMMUNITY HEALTH CENTERS

Senator HARKIN. Maybe we will do that later on some time. OK, thank you, Dr. Goodwin.

Dr. Harmon, just a couple of quick ones. I want to talk about community health centers. It has been years since there were any new starts. There are no centers in rural areas of Iowa, Montana, North Dakota, Nebraska, many of the areas in our heartland.

Last year we added $20 million to the community health center program. Yet no new starts were considered. Can you tell me why? Do you know why?

Dr. HARMON. Well, Senator, it was felt that there were other priorities, and some of those are reflected in the 1991 budget proposal. Trying to recruit and retain physicians has been one of the top priorities, needing to increase the pay and so forth to try to get those practitioners to come or to stay on.

We have been making gradual progress in the resources going to the rural centers. It has been climbing steadily toward a 50-50 split in the funding. The placement of the physicians has actually been going mostly to the rural areas, which are indeed the most needy and among the hardest to fill.

Also, it is felt—and some of this is reflected in the 1991 budget proposal in the housing project matter—that creating satellites to existing centers may be one of the best ways to go, as opposed to starting from scratch with brand new freestanding centers.

So we think there are other ways to address the rural areas than just brand new starts.

MATERNAL AND CHILD HEALTH HANDBOOK

Senator HARKIN. On the maternal and child health block grant last year, we put in money for a handbook. Do you know when those handbooks are going to be ready?

Dr. **Harmon**. The handbook, some call it a passport and so forth, we will be going through some development and some field testing on that matter, and we hope to have that developed during this fiscal year.

It is a major undertaking and it costs a lot more than the money appropriated. So we need to start off with some pilot testing and get it right.

NATIONAL HEALTH SERVICE CORPS

Senator **Harkin**. OK. Let me pick up on something that Senator Bumpers was asking you about, and that is the National Service Corps. Let me just tell you what it means to my State of Iowa. There are 23 health manpower shortage areas, where the physician to population ratio is 1 to 3,500. In 1988, 26 Corps doctors were practicing in those areas. Now there are just 12, and 7 of them will complete their service obligation this year.

According to your staff, no new placements are planned for Iowa in 1990 or 1991. So we have gone from 26 in 1988 down to—well, we will just have about 5 left next year.

Why are we not getting any new placements?

Dr. **Harmon**. Well, again we have the problem of the Corps is winding down, and again we have about 1,300 assignees out in the field and we need about 4,200 to remove the health manpower shortage area designation. We are hoping to start rebuilding that with the proposal for 1991.

We have about three or four times as many leaving as are coming in. They are very scarce. I would point out that as they become available, the priority tends to be the rural areas for the obligated scholars.

So we are doing our best and we are trying to rebuild that. We are pleased that there is a proposal for more scholarships in the 1991 budget. With regard to your State of Iowa, we are recruiting a total of 11 physicians this year, including 2 scholarship obligors.

Senator **Harkin**. Here is the data that I have. There are 1,250 vacant corps sites now, right now. In 1990, 630 doctors will complete their service obligation; only 137 graduates will start theirs. Over the next 3 years, 800 more doctors will finish their requirements, but only 169 will start.

How are you going to boost that? I mean, like you said, you are winding down the Health Corps Service right now.

Dr. **Harmon**. Of course, this started some time ago with the winddown of the Corps scholarships, and we are pleased it is restarting. We do have some funding in the $55 million increase for loan repayment programs working with the States, and that is the way to get persons to come in immediately.

It is a little harder to get them to go to the neediest areas. But working with the States—we currently have seven States on board—we will be gradually, or actually pretty quickly, getting more assignees into those sites through loan repayment programs, if this is approved.

Senator **Harkin**. Why can you not assign them to the neediest areas?

Dr. **Harmon**. Because there is a matter of voluntarism in the loan repayment program. A medical student coming out of residency with, say, $70,000 of loans can choose to go work somewhere else and try to pay those off, or to get them paid off through this new program.

So they tend to not want to go to the hardcore areas. The scholarship program is the best for that. That is why we need both.

Senator **Harkin**. How much more money would it take to get the scholarship program back up and fully funded?

Dr. **Harmon**. Obviously, a lot of money. I do not have the exact figure at hand. But again, the overall need is over 4,000.

Senator **Harkin**. That is about the only way we are going to get them in these rural areas, right?

Dr. **Harmon**. In the neediest, most remote rural areas, so far that is the best way. I might point out, there are other alternatives in rural areas: Physicians working with nurse-practitioners and physician assistants. So we need to explore a variety of alternatives.

Senator **Harkin**. But the core of it still has to be the Corps.

Dr. **Harmon**. I agree.

Senator **Harkin**. And if that Corps is not there, I do not care what else you build up. Sure, we need the nurse-practitioners, we need the other health care, physician's assistants and everything else. They are all a very vital part of it.

But you still have to have that central medical doctor there at the core of it.

Dr. **Harmon**. I agree.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

AIDS

Question. What are the projections for new cases?

Answer. In total, over 121,500 AIDS cases and more than 72,500 AIDS-related deaths have been reported in the U.S. since 1981 (data as of January 31, 1990). In 1989, 35,238 new cases of AIDS were reported, an increase of 3,042, or 9 percent, over 1988. The PHS estimates that between 650,000 and 1.4 million people in the U.S. are infected with the human immunodeficiency virus. Natural history studies suggest that most HIV-infected persons will become ill at some time after infection, even though this may not occur for 8 to 10 years or even longer. Because of this, it is expected that the number of newly diagnosed cases of AIDS will continue to increase in the U.S. at least through FY 1993. The PHS estimates that through 1993, between 390,000 and 480,000 persons cumulatively will have been diagnosed with AIDS.

Question. What progress has been made in treating AIDS?

Answer. The progress in treating AIDS during 1989 includes the following significant accomplishments: AZT has been shown effective in delaying the onset of AIDS in asymptomatic people with CD4+ counts less than 500. Lower doses of AZT are as effective as standard dosage and less toxic. A new drug dideoxyisine (ddI) is currently being tested in Phase II clinical trials and has been available for AIDS patients who cannot tolerate AZT. Approved January 1990, fluconazole has been approved by FDA for treating some of the conditions resulting from the AIDS infection. This brings the total approved FDA drugs to nine.

PHS has also launched the community programs for clinical research on AIDS. This program will improve access to clinical research activities for both health care providers and HIV-infected persons who previously have not had the opportunity for such participation. This program also will enable unrepresented minorities, women and drug users to gain access into the AIDS clinical studies.

Question. Why have you dropped the funding for AZT?

Answer. Our basic concern is to ensure that care for AIDS and HIV infected persons be delivered in the same manner as other patients with similarly severe illnesses. We are concerned about seeking solutions that foster a separate or parallel approach that is not integrated with existing services and systems. In addition, many private insurers and all STate Medicaid programs now pay for some HIV treatment drugs, such as AZT. The PHS believes that the categorical funds for AIDS drug reimbursement have served their transitional purpose and are no longer required.

Question. What is the focus of this increase in AIDS funds in the various Public Health Service agencies?

Answer. The FY 1991 President's Budget request includes $1.7 billion for research, prevention, and other activities connected with the battle against AIDS. All agencies of the Public Health Service support activities in the fight against this disease. Selected increases by agency are provided as follows:

- FDA - increase of $7 million (12 percent) over 1990 to continue the regulatory activities for therapeutics, vaccines, diagnostics, blood and blood products and medical devices related to HIV infection and AIDS.

- HRSA - net decrease of $40 million from 1990 reflects increases to Education and Training Center activities, Community Health Center programs and Pediatric AIDS grants. These increases are offset by the elimination of the drug reimbursement, home health care, and subacute care programs, which should be funded through Medicare, Medicaid, State activities, and private health insurance.

- CDC - increase of $66 million (15 percent) over 1990 to support increases in evaluations to document the effectiveness of various counseling techniques on behavior and subsequent HIV serostatus among high-risk persons, and evaluations to assess the effectiveness of street outreach for IV drug users and in their sex partners. Also includes an increase in efforts to prevent HIV transmission among women and infants and resources targeted to youth who are most likely to engage in high-risk behaviors.

- NIH - increase of $57 million (8 percent) over 1990 to fund additional clinical trials, vaccine development and other research activities in AIDS and HIV infection with increasing emphasis on the role of co-factors in HIV infection and disease progression.

- ADAMHA - increase of $15 million (7 percent) over 1990 to support increased biomedical research, neuroscience and neuropsychiatric research, research training, and risk assessment and prevention activities. Also, includes a slight increase in buildings and facilities.

- AHCPR - increase of $2 million (24 percent) over 1990 to expand AIDS cost and service utilization survey to address the health resource utilization of the asymptomatic population.

- OASH - increase of $1 million (11 percent) over 1990 for improvements in the National AIDS Program Office and support for Minority Community Coalition Grants.

PROJECTIONS

Question. Last year you told us that between 1,000,000 and 1,500,000 Americans were HIV positive. Now we see by your projection that 600,000 to 1,400,000 are infected.

What has caused you to reduce your estimates?

Answer. Estimate of HIV Infection--CDC now estimates that approximately 1 million persons in the United States are infected with HIV. This calculation is based on HIV survey data that became available in 1989, on analyses using statistical methodologies developed during the last few years, and other methodologies developed over the last several months. These methods yield individual estimates of about 650,000 to 1,400,000 infected persons. The wide range reflects inherent uncertainties in past surveys and differing assumptions underlying earlier statistical systems. The current estimate is at the lower end of the range of 1 to 1.5 million persons infected provided in 1986. That estimate was based on very limited data, and few HIV surveys (the antibody test was licensed in 1985). We now estimate that about 750,000 people were infected with HIV by early 1986.

Projections for AIDS Cases--Late in 1989, CDC convened a meeting of experts--more than half from outside the Public Health Service--to estimate the number of AIDS cases that would be diagnosed in the United States from 1989 through 1993. They predicted that the number of cases diagnosed would increase in each successive year. The middle of the range of projections for each year is about 15 percent less than the corresponding prediction by the Public Health Service in June 1988.

Through 1988, we estimate that 120,000 AIDS cases were diagnosed in the United States and that between 44,000 and 50,000 persons were diagnosed with AIDS in 1989. We project that 390,000 and 480,000 cumulative AIDS cases will have been diagnosed by the end of 1993.

PERINATAL AIDS/OUTREACH TO HIGH-RISK WOMEN

Question. In 1988, 70 percent of babies born HIV-positive were infected as a result of IV drug abuse by the mother of her sexual partner. As I understand it, the OASH budget request to OMB for Fiscal Year 1990 contained a new $10 million initiative to provide outreach and family planning counseling services to high-risk women.

Did your FY 1991 budget to OMB contain such a request?

Answer. The OASH budget sent to OMB did not contain a specific request of $10 million for outreach and family planning counseling services to high-risk women as those activities were included within the request sent to OMB for the Centers for Disease Control (CDC).

The CDC request for FY 1991 CDC HIV/AIDS budget contains an increase of $14 million over the FY 1990 level, for Perinatal AIDS Prevention Projects to prevent transmission among women and infants. Women now comprise ten percent of reported cases of AIDS, and the prevalence of HIV infection in women of reproductive age is increasing. This increase would permit CDC to initiate targeted interventions in extremely high incidence cities and to conduct HIV-related epidemiologic studies; for example, studies to assess the determinants of contraceptive use and the integration of these determinants into HIV prevention strategies.

The CDC budget also contains funds for counseling/testing/partner notification. These resources are spent through a host of entities including family planning clinics.

Question. Would you support such a program as a means to reduce the tragic rate of perinatal AIDS in this country?

Answer. We support such program activities through resources requested in the CDC HIV/AIDS FY 1991 budget request to Congress.

Question. Last year we appropriated a total of $137 million for Pediatric AIDS?

What is the total requested for Pediatric AIDS for FY 1991?

Answer. The total requested for Pediatric AIDS in FY 1991 is $172 million.

AIDS PROGRAM OFFICE

Question. The Administration is no longer requesting a consolidated AIDS budget through the OASH, yet is requesting a budget increase and five more staff positions for the National AIDS Program Office.

> -- With the Public Health Service agencies overseeing their own AIDS budgets, what is the rationale for increasing the budget and staffing level of the National AIDS Program Office?

Answer. Although the Administration is no longer requesting a consolidated AIDS budget, the Public Health Service (PHS) is taking steps to improve the analysis and management control of AIDS/HIV budgets and plans through enhanced National AIDS Program Office (NAPO) activities. NAPO is responsible for coordinating Public Health Service (PHS) HIV/AIDS efforts, including reviewing and analyzing PHS agency HIV/AIDS budget requests, setting priorities, and recommending appropriate budget levels to the Assistant Secretary for Health. The increase requested in the budget will be used to analyze, monitor, and track the AIDS/HIV budget by category and by PHS agency. Additional staff provided in the budget request will work with the PHS agencies and other staff offices and program offices of the ASH and Departmental components in carrying out the increased responsibilities of the office.

Question. How does the Office coordinate HRSA and CDC programs providing early interventions for persons with HIV infection and ensure they enter treatment promptly?

Answer. NAPO has played a major role in facilitating communication between agencies resulting in increased coordination and leading to both regular informal collaboration and formalized cooperative agreements.

The bi-weekly meetings of the PHS Executive Task Force on AIDS (attended by agency AIDS Coordinators) and HIV Leadership Group (attended by agency heads, agency AIDS Coordinators, and key OASH and NAPO staff and chaired by the Assistant Secretary for Health) promote and facilitate inter-agency cooperation by providing for a for discussion of activities among agencies and within the PHS.

Within this framework, CDC and HRSA have entered into an inter-agency agreement to fund projects in three Community Health Centers. These Centers demonstrate the linkage of prevention and education activities with treatment for HIV-related conditions. These two agencies communicate directly regarding implementation of this agreement, and use established mechanisms of these Centers to assist persons in obtaining prompt treatment.

Question. Dr. Mason, last year you wrote noting that it was important to continue funding research demonstration projects that provided bleach to IV drug abusers. Can you tell us about the preliminary findings of this research?

Answer. Investigations have demonstrated the ability of bleach (sodium hypochlorite) to inactivate free and cell-associated HIV in the test tube with bleach concentrations as low as 1 part bleach per 200 parts water.

ADAMHA is currently studying the effect of bleach in vivo, that is, the effectiveness of bleach to inactivate HIV directly in blood. A preliminary study suggests that bleach may need to be used at higher concentrations in vivo in order to inactivate HIV, particularly if mechanical cleaning of the needle and works has not been done.

Question. Does the Administration support continued research on the impact of providing bleach on reducing the spread of the HIV virus and AIDS?

Answer. Providing bleach as part of a comprehensive drug abuse outreach program gives drug users the means to protect themselves and others from a fatal infection until they can be brought into treatment. Programs of this type, currently funded by the Department, show no evidence of having contributed to the spread of drug abuse. If they did, we would not support them. Research reported at the Fifth International Conference on AIDS suggests that drug abusers could and did learn to change high-risk needle-sharing behavior, including cleaning their "works" with bleach. There is a limited and appropriate role for the distribution of bleach to help contain the spread of HIV infection.

EDUCATION/YOUTH

Question. Since the beginning of the AIDS epidemic, our nation's youth have become infected with HIV at a significant rate, as evidenced by the proportion of persons aged 20-29 who have been diagnosed with AIDS. The largest single AIDS increase requested is $66 million for CDC education programs.

To what extent are schools providing HIV education for students at each grade level?

Answer. In 1989, several of the CDC-funded State and local departments of education conducted surveys of the availability of HIV education and of comprehensive school health education. Data from the eleven States that has a school response rate of greater than 70 percent were analyzed. In these states, preliminary analysis showed that:

- o an average of 90 percent of the schools provided some form of HIV education;
- o an average of about 62 percent of the students in these States received HIV education.

As each funded State and city further develops its HIV comprehensive health education programs, improvement will be noted in the availability of school health education. In addition, it is vital that programs are implemented to help out-of-school youth also avoid behaviors that put them at risk of a variety of health problems, including HIV infection.

Question. There are approximately 9 million youth aged 14 to 21 who do not attend school or college.

What is CDC doing to provide HIV education for these out-of-school youth?

Answer. The request for fiscal year 1991 includes an increase for an initiative to prevent HIV infection among out-of-school youth. The nine million school-aged youth who do not attend school or college are a hard-to-reach, high-risk population that until now have not been the focus of needed prevention efforts. The initiative will begin the process of providing effective prevention services by supporting needed research into the determinants of high-risk behaviors among out-of-school youth and providing funding to high incidence cities to develop, implement, and coordinate the efforts of youth-serving organizations. These organizations will be implementing HIV education in a variety of settings and will be employing strategies for increased and improved outreach and intervention activities.

Question. What is CDC doing to provide HIV education for college students?

Answer. In fiscal year 1990, CDC will provide funding to a college or university in selected States to establish a State-wide HIV education consortium of institutions of higher education. Activities to be conducted include: disseminating college-level educational materials; training university staff and students to implement HIV education programs; coordinating efforts of campus programs; and working with education agencies within the State to provide pre-service and in-service training for teachers.

The objective is to increase the number of colleges and universities providing HIV education and the number of students receiving this education.

OBJECTIVES FOR THE YEAR 2000

Question. Dr. Mason, you have a strong background in public health, and have said many times that our efforts in preventive health care are sorely lacking. Last week I introduced the Health Objectives for the Year 2000 Act. This legislation would give State and local public health agencies the means to plan and implement health objectives for the Year 2000 by increasing the authorization for the Preventive Health Care block grant to $300,000,000. The funding for this block grant has been frozen at about $85 million for a decade.

What is your view of the need to increase funding for preventive health programs?

Answer. National health care expenditures total about $500 billion each year. Forty percent of that amount is spent on hospital care, about 20 percent on physician services, and 8 percent on nursing home care. Government public health expenditures represent only 3 percent of the total. Thus, by far the majority of the money this country spends on health care goes for treatment and cure; only a small fraction is spent on prevention. We know that greater investment in prevention would reduce years of potential life lost and improve quality of life. I believe it is important to increase expenditures for prevention. In fact, our FY 1991 budget includes over $6 billion for prevention, an increase of $454 million over FY 1990. Let me stress that prevention is a cooperative venture involving the Federal and State governments and the private sector. Most importantly, individual responsibility is a key factor in success.

The Preventive Health and Health Services Block Grant represents only 1 percent of total State health agency expenditures in the United States. Funding of many public health programs depends on this grant for support. States have had to increase their contributions to support program services to enhance block grant funding.

Question. Can we get there with rhetoric alone?

Answer. No. It is important that many diverse groups and organizations support the efforts to achieve the Year 2000 Objectives, and that each State address national health policy issues as well as its own particular concerns.

HEALTH OBJECTIVES

Question. I understand that we met about one half of the 1990 goals; we failed to meet one-fourth of them and we are not sure about the remaining one-fourth because of the lack of data. Dr. Mason, could you tell us which objectives or goals have been met and which ones have not been met?

Answer. We have now reached the final year of the 1990 Health Objectives for the Nation project. At the end of calendar year 1990, data will be collected to provide a thorough final report on objectives. The report will be available during Fiscal Year 1992.

Based on the midcourse review of the objectives, conducted in 1985, we project that approximately one-half of the objectives will be accomplished as targeted, approximately one-quarter will fall short of the mark, and one-quarter lack data to support a determination.

Those areas that we believe will be successfully met are: reducing unintentional injuries, controlling high blood pressure, achieving gains in dental health, controlling vaccine-preventable infectious diseases of childhood, and making significant strides to reduce the prevalence of smoking.

The areas we are concerned about include: rates of infant mortality and low birth weight among minority populations, recent increases in motor vehicle-related crash fatalities, homicide and suicide rates among segments of the adolescent and young adult population, teenage pregnancy, and the rate of hepatitis B infection (the risk groups for which closely parallel those for AIDS).

NATIONAL CENTER FOR HEALTH STATISTICS

Question. I see that your budget request for the National Center for Health Statistics is flat. [$44.9 million, up $13,000]

Can you develop adequate data to track the health goals for the Year 2000 with a flat budget for the National Center for Health Statistics?

Answer. The National Center for Health Statistics (NCHS) has the technology in place to provide an invaluable component to implementation of the Year 2000 Objectives. Success in achieving the objectives depends on the ability to track progress. Surveillance systems must be put in place and NCHS will be responsible for this task.

NCHS has many other important activities. NCHS presently is implementing the National Health and Nutrition Examination Survey III, the most ambitious national health survey ever undertaken. NCHS continues to conduct the National Health Interview Survey, which gathers health-related data for many other PHS agencies. NCHS also conducts the National Survey of Family Growth, the National Maternal and Infant Health Survey, and the National Health Care Survey. In addition NCHS is the agency responsible for collecting and disseminating all of our Nation's vital statistics.

Few of the demands of the Year 2000 Objectives can be met through existing surveys and data collections. Our program managers are careful to balance the activities in support of the Objectives and NCHS' other long-standing responsibilities. Although the budget request remain flat, the mission of NCHS will be able to meet increased data needs such as those required by the Year 2000 Objectives.

REDUCING HEALTH CARE SPENDING

Question. A few years ago, we started hearing a lot about technology assessment and the great promise it held for reducing health care expenditures through promoting "appropriate" utilization of health services. So far, the federal government has spent millions on technology assessment, but health care costs go up annually about three times as fast as the inflation rate. How will the medical treatment effectiveness initiative be different from past work in technology assessment, and how will treatment effectiveness studies be used to reduce federal spending on health care?

Answer. Medical technology assessment is the investigation of the appropriate use, efficacy, cost effectiveness, diffusion, and ethical, legal and economic effects of specific devices, and medical and surgical procedures. In contrast, medical treatment effectiveness emphasizes empirical comparison of alternative treatments for the same condition, including the possibilities of "watchful waiting" and decisions not to treat. It asks what treatments work best and whether patients benefit. Effectiveness research focuses on health problems and interventions for which the risks and costs are particularly high and treatment for which patient outcomes are particularly variable or uncertain. In addition to clinical outcomes, patients' perceptions of their functional ability, health status, and satisfaction with care are also to be addressed in medical treatment effectiveness research.

Question. What, if any, are the projected savings?

Answer. Research findings of the Medical Treatment Effectiveness Program (MEDTEP) in the Agency for Health Care Policy and Research may have considerable implications for health care spending and cost containment. Reduction in inappropriate variation in the use of health care services and procedures could generate substantial savings. However, the focus of the MEDTEP research program is to identify those health care services and procedures that improve quality of care, improve patient outcomes, and improve the patient's quality of life. It is possible that the optimum treatment is more costly than the alternatives.

Question. Will treatment effectiveness studies affect Medicaid and Medicare payment policies?

Answer. MEDTEP is not designed to identify cost containment measures, to specify necessary reductions in federal spending on health care services, or to directly affect Medicaid and Medicare payment policies. Instead, it is MEDTEP's production and documentation of scientific research findings, together with active dissemination of these findings, that will lead to more informed clinical decisionmaking and a more effective and efficient health care system.

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Question. Dr. Mason, the new Agency for Health Care Policy and Research combines the new medical effectiveness research and the other health service research functions. Is the new office fully functioning now and when will we have a permanent director in place?

Answer. The Agency for Health Care Policy and Research was established with enactment of the Omnibus Budget Reconciliation Act of 1989, on December 19, 1989. The Agency succeeds the National Center for Health Services Research and Health Care Technology Assessment which was previously included in the Office of the Assistant Secretary for Health. Formal transfer documents and an organizational structure have been prepared and submitted to the Secretary for approval. The Secretary will appoint a permanent Administrator for the Agency. Dr. J. Jarrett Clinton has been serving as the Acting Administrator since December 27, 1989.

MEDICAL EFFECTIVENESS

Question. Dr. Mason, your total spending plan for medical effectiveness research for fiscal year 1991 is $48.5 million. This comes from three sources:

Transfers from other public health agencies	$6.5 million
Transfers from the Medicare Trust Fund.........	$28.0 million
Requests for appropriation.....................	$14.0 million

This compares to the FY 1991 authorizations of $75 million. Please tell the Committee about the overall importance of this effort and what diseases or disorders will be addressed by this research in the first several years.

Answer. Within the Agency for Health Care Policy and Research (AHCPR), the Medical Treatment Effectiveness Program (MEDTEP) will be implemented through several related activities: medical effectiveness/ patient outcomes research; data base development; dissemination of findings; and development of practice guidelines.

- MEDTEP research has clear capacity to reduce inappropriate variations in clinical decisionmaking and to improve the outcomes of health care:
  - First, as demonstrated by the research of John Wennberg and others in Maine, Vermont, and Iowa, physicians will alter their behavior when presented with evidence that their practice patterns significantly deviate from those of their colleagues. MEDTEP will support effective dissemination of research findings regarding practice variations. More basically, MEDTEP will help to resolve the clinical uncertainties that often underlie variations in practice and will support active dissemination of those findings.
  - Second, in the legislative negotiations over the Resource-Based Relative Value Scale (RBRVS) physician payment system, the AMA considered a strong patient outcomes research program essential. This suggests that organized medicine considers this research important.
  - Third, in developing dissemination strategies targeted to practicing clinicians, AHCPR intends to apply two important lessons from earlier work: 1) positive change in physician behavior can be accomplished by providing physicians nonthreatening, educational feedback in a collegial setting; and 2) educational programs must be ongoing and reinforce the message.
  - Fourth, MEDTEP has significance for saving, extending, and improving the quality of lives, improving the quality of health care for Medicare beneficiaries and other patients; and increasing and maintaining patients' functional abilities by identifying treatments that are ineffective or less effective than available alternatives.
  - Fifth, MEDTEP research will be a major resource for a collaborative governmental and private effort to develop practice guidelines regarding the appropriate use of health care services and procedures. AHCPR's Office of the Forum for Quality and Effectiveness in Health Care

will support panels of experts in efforts to develop guidelines, standards, review criteria, and performance measures to assess and assure quality of care.

o In FY 1990 and FY 1991, AHCPR will continue support of 5 Patient Outcomes Research Teams (PORTs) that are developing and testing methods to reduce inappropriate variations in the treatment of:

-- Low back pain
-- Heart attacks
-- Cataracts
-- Prostate gland enlargement
-- Knee replacement

o During FY 1990 and FY 1991, several new teams will be funded to identify and analyze the outcomes of alternative practice patterns, including the effects on patient survival, quality of life, and cost of care. Since all grant applications first have to undergo peer review, a list of diseases or disorders to be studied is tentative. However, possible topics include:

-- Hip fracture and replacement
-- Diabetes
-- Cerebral vascular disease
-- Breast cancer
-- Congestive heart failure
-- Pneumonia
-- Biliary tract disease and cholecystectomy
-- Colon cancer
-- Hysterectomy
-- Osteoarthritis
-- Ischemic heart disease

RURAL HEALTH CARE - AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Question. Dr. Mason, tell us what the new Agency will be doing this year and what's planned for FY91 in rural health care and the rural health research agenda, and about how much of your budget will be devoted to these efforts. What is the Agency doing to build the research capacity of institutions in rural areas?

Answer. In FY 1989, the former National Center for Health Services Research (NCHSR) funded four new extramural grants with the $500,000 directly appropriated to NCHSR for rural health care research. All four will be continued in FY 1990 by AHCPR. Topics include:

-- Why rural Maine residents using federally-funded community health centers have lower rates of hospitalization than non-CHC users;

-- The barriers to access to health care faced by the rural uninsured and medically indigent in Nebraska;

-- The types of alternative health services that the rural elderly, rural poor and rural Blacks use, either because of access barriers to traditional health care services or the availability of alternatives; and

-- Urban/rural differences in survival rates and utilization of health and community-based services by the elderly.

In addition, in FY 1989 we funded one ongoing project and one new project out of evaluation funds, totalling $179,000, that examine rural health care issues:

-- The relative effectiveness of various management strategies by rural hospitals to identify the most successful strategies;

-- Variations in resource use, costs and outcomes among rural and urban obstetricians, family practitioners and nurse midwives in Washington State.

In FY 1990 and 1991, AHCPR will spend $2.5 million on rural health care. In addition, AHCPR plans to fund additional new grants dealing with rural health care issues (some of which may be jointly funded in FY 1990 with the National Center for Nursing Research). For example, we will be funding a grant to a rural researcher who has established a reputation as a leader in the field of prevention. He will be testing ways to improve the frequency with which physicians provide health promotion/disease prevention services to their patients. Two of the three test sites are in Appalachia. The Agency will also support a study to improve health and reduce health care costs for children of low-income families in rural areas by increasing utilization of Early and Periodic Screening, Diagnosis and Treatment (EPSDT), a Federal program providing comprehensive health promotion/disease prevention services for Medicaid-eligible individuals from birth to age 21.

-- The AHCPR's intramural Hospital Studies Program will soon release information on the most frequent diagnosis and procedures performed in small and large, rural and urban hospitals. These statistics allow urban-rural comparisons on hospital charges and lengths of stay, types of patients, death rates, and typical payers for hospital services for the fifty most frequent procedures, diseases, and DRGs found in these hospitals.

-- This same research program is studying financial distress among U.S. hospitals in the 1980s -- one dimension will explore differences in financial viability between rural areas with low population density and other rural and urban areas.

-- On February 9, AHCPR, through its User Liaison Program, convened a meeting of rural researchers, and County, State, and Federal policymakers to gain their views on new research that would be valuable to them as they address rural health care issues.

In total, $2.5 million will be devoted to rural health activities in FY 1990, $1.2 million from budget authority and $1.3 million from PHS evaluation funds.

Technical Assistance

Staff of AHCPR are finalizing plans with the Office of Rural Health Policy to develop three types of programs of technical assistance.

- First, we will provide technical assistance to the five rural research centers funded in the HRSA budget.
- Second, the User Liaison Program has scheduled technical assistance activities for the States of Idaho and Alabama (and possibly Vermont and North Dakota) pertaining to aspects of rural health care.
- Third, we will conduct public technical assistance workshops open to all rural researchers.
    - Initially, we will schedule sessions at the five rural research centers and at the National Rural Health Association meeting this May.
    - In the future, we intend to schedule sessions in areas that are not near existing rural research center sites.

One of the goals of these workshops for rural health researchers and rural institutions is to improve their capacity to develop scientifically sound research proposals.

OFFICE OF MINORITY HEALTH

Question. As part of the Secretary's Minority Health Improvement Initiative, the Fiscal Year 1991 budget requests an increase in funding for the Office of Minority Health from about $8 million in FY 90 to almost $20 million in FY 91 and an FTE increase from 17 positions to 30. Does this request reflect a change in the Office's mission?

Answer. No, the basic mission of the Office of Minority Health will remain to serve as the principal focus for ensuring implementation of the Recommendations of the Report of the Secretary's Task Force on Black and Minority Health; and to serve a role as catalyst within the Public Health Service to stimulate and coordinate efforts to improve the health status of racial/ethnic minorities. The additional resources will allow for a significant expansion of that effort.

Question. What projects will the office undertake, and how will they be coordinated with the other minority health initiatives in the budget request?

Answer. The additional resources for the Office of Minority Health will provide for expansion of grants to support community-based coalitions, enhanced health promotion/health education information dissemination; broader collaborative efforts with private/voluntary sector organizations (e.g. March of Dimes, American Diabetes Association, American Lung Association) educational entities (e.g. Hispanic Association of Colleges and Universities, National Association for Equal Opportunity in Higher Education), religious organizations (e.g. National Congress of Black Churches), et.al.

OMH will expand its current coordination process to assure that the Health Professions Development Committee and its goals and objectives are linked to the new budget initiatives. OMH will also provide key support to the new Interdepartmental Health Sciences Coordinating Committee which will link Federal programs targeting minority students for health, science and technology education.

Question. What work will the office be doing related to AIDS?

Answer. OMH will expand the existing programs for Coalition Grants and AIDS/HIV Prevention/Education Grants. In addition, the Office will coordinate several regional meetings and a national meeting to focus on current problems and issues facing minority communities as a result of the HIV epidemic. Special efforts will be made to develop race/ethnic specific messages for various media presentations; to consult with a broader base of community organizations; and to coordinate programs with other PHS agencies more effectively.

MINORITY HEALTH INITIATIVE

Question. The budget proposes $107 million for minority health projects in HRSA, including $35 million for health clinics in federal housing projects, $55 million to recruit disadvantaged and minority students into the National Health Service Corps, $5 million for communities and institutions to recruit health professionals, and $12 million for faculty development at minority health professions schools. In addition, the budget requests $12 million for excellence in minority health education grants.

Which schools would be eligible for grants to minority health professions schools and for faculty development?

Answer. The health professions schools eligible to compete for grants under the H.P. Institutional Development Faculty Development Component are as follows:

School	Discipline	State
Drew	Medicine	California
Meharry Medical College	Medicine	Tennessee
Meharry Medical College	Dentistry	Tennessee
Morehouse	Medicine	Georgia
Tuskegee University	Veterinary Medicine	Alabama
University of Hawaii	Public Health	Hawaii
University of Hawaii	Medicine	Hawaii
Ponce	Medicine	Puerto Rico
Universidad Central Del Caribe	Medicine	Puerto Rico
University of Puerto Rico	Medicine	Puerto Rico
University of Puerto Rico	Dentistry	Puerto Rico
University of Puerto Rico	Public Health	Puerto Rico

The pharmacy and nursing schools and institution with health administration programs eligible to compete for grants under the H.P. Institutional Development Academic Improvement Component are as follows:

Name	Discipline	State
Texas Southern	Pharmacy	Texas
Xavier	Pharmacy	Louisiana
Florida A & M	Pharmacy	Florida
Howard University	Pharmacy	District of Columbia

University of Puerto Rico	Pharmacy	Puerto Rico
Bishop State Jr. College	Nursing	Alabama
Lawson State Comm. College	Nursing	Alabama
Oakwood College	Nursing	Alabama
Tuskegee University	Nursing	Alabama
University of Arkansas	Nursing	Arkansas
Delaware State College	Nursing	Delaware
Howard University	Nursing	District of Columbia
University of the District	Nursing	District of Columbia
Bethune-Cookman College	Nursing	Florida
Florida A & M University	Nursing	Florida
Albany State College	Nursing	Georgia
Morris Brown College	Nursing	Georgia
Kentucky State University	Nursing	Kentucky
Dillard University	Nursing	Louisiana
Grambling State University	Nursing	Louisiana
Southern University	Nursing	Louisiana
Bowie State College	Nursing	Maryland
Coppin State College	Nursing	Maryland
Shaw College at Detroit	Nursing	Michigan
Alcron State University	Nursing	Mississippi
Lincoln University	Nursing	Missouri
North Carolina A & T State University	Nursing	North Carolina
North Carolina Central University	Nursing	North Carolina
Winston-Salem State University	Nursing	North Carolina
Langston University	Nursing	Oklahoma
Puerto Rico (16 schools)	Nursing	Puerto Rico
South Carolina State College	Nursing	South Carolina
Prairie View A & M University	Nursing	Texas
Hampton University	Nursing	Virginia
Virginia State College	Nursing	Virginia
University of Hawaii	Nursing	Hawaii
Howard University	Health Admin.	District of Columbia
University of Puerto Rico	Health Admin.	Puerto Rico
Meharry	Health Admin.	Tennessee
Florida A & M	Health Admin.	Florida

Question. How will the $35 million program to establish clinics in federal housing projects work for rural areas?

Answer. The $35 million program to establish clinics in association with public housing projects is part of the Secretary's minority health initiative designed to improve access to care for minorities. The overwhelming percentage of minorities reside in urban areas (81 percent of the black population). It is therefore expected that the major portion of these funds would go to toward addressing the needs of the underserved (minority) population residing in urban areas.

As with other programs, the need for services and the capability of the service delivery organization to effectively and efficiently provide services will be evaluated.

Question. Will the Administration propose legislation to authorize the minority health initiatives?

Answer. The Administration is not submitting legislation for those programs. The Department will work closely with the Congress on the final legislation.

CONTRACEPTIVE RESEARCH

Question. The United States used to be a world leader in contraception technology and research. Clearly, safe and convenient methods of contraception are the key to reducing the incidence of abortion.

How much contraceptive research does the Department currently support?

Answer. Within the Department, the focus for contraceptive research is in the programs of the National Institute of Child Health and Human Development (NICHD). The Institute supports a broad range of research in this area including contraceptive development and evaluation, basic research in the reproductive sciences, and behavioral studies related to contraceptive use. The NICHD FY 1990 estimate for contraceptive research is $20.5 million.

TEENAGE SMOKING

Question. The Surgeon General of the United States has labeled smoking the most important preventable cause of death in our society. Currently over four million teenagers are hooked on this legal drug. Because most adult smokers became addicted when they were teenagers, you can predict that preventing teen smoking probably would reduce the adult population that smokes and save a great deal of time.

In a report issued last June, the GAO found that an increase in cigarette excise taxes would bring about a significant reduction in the number of teenage smokers. GAO estimates that raising the excise taxes by about 20 cents a pack would result in over 500,000 fewer smokers, and would lead to about 125,000 fewer premature deaths.

Do you support an increase in the cigarette excise tax, and if not, why not?

Answer. Increases in the price of cigarettes have been shown to decrease smoking, particularly among adolescents (because adolescents are more price-sensitive than adults). Because excise taxes increase price, reduce demand, and reduce consumption, they are viewed as an effective tobacco control intervention -- particularly when included as part of a comprehensive intervention strategy.

As you may know, all State governments and nearly 400 localities impose cigarette taxes which have an effect similar to that of a Federal excise tax increase. In fact, several jurisdictions have earmarked portions of their excise tax revenues to fund tobacco control interventions and other worthwhile initiatives. I would encourage all jurisdictions to consider pricing adjustments that would have a direct effect on their revenue and health of their residents.

Question. What is the Department doing to prevent and reduce smoking among young people?

Answer. It is the mission of CDC's Office on Smoking and Health (OSH) to prevent death, disease, and disability caused by tobacco use and to coordinate a national program to reduce the prevalence of tobacco use in the overall population, as well as in specific target groups such as teenagers. The OSH is conducting a national prevalence survey and special analyses of teenager smoking behavior, as well as targeting specific information activities to reach this audience. During these past 10 years. OSH has targeted a number of its information efforts to teenage audiences. Television, radio, and printed material have been produced and widely distributed.

In addition, CDC works with State and Territorial education agencies, national organization, and other youth-serving agencies to help schools develop, evaluate, and improve health education programs that address a full range of health risk behaviors among youth, which include smoking. CDC's evaluation demonstrated that comprehensive school health education is an effective means of helping children improve their health knowledge and attitudes and decreasing the likelihood that they will adopt unhealthy behaviors like smoking.

AIDS MEDIA-BASED PROGRAM

The National Academy of Sciences recently published recommendations for evaluating CDC's AIDS prevention efforts, specifically including the media-based program.

Question. What evaluation is being done of the national media-based AIDS information efforts?

Answer. CDC is establishing measurable objectives for the next 2 years of the national HIV information/education program, based on priority recommendations from key Public Health Service officials; national, State, and local agencies; the National Academy of Sciences; and on extensive social marketing research. Systems are being established to determine the impact of messages on the public during the June 1990 information/education program. This will allow CDC to examine the role of its television PSAs and other components of the information/education program in the educational/prevention process.

Question. What evaluation is being done of the AIDS Hotline and the AIDs Information and Clearinghouse?

Answer. The quality of the National AIDS Hotline services is assessed monthly through a contract with the Public Health Foundation. Assessment data indicate that 97 percent of the calls are answered on the first attempt, indicating no significant delay in getting information and that the responses are timely, courteous, and accurate.

Evaluation of listed materials represents the most important assessment of the Clearinghouse at this time. An important subcontract is being awarded to the American Foundation for AIDS Research to conduct evaluations based on the currency of material, appropriateness for target groups, reading level and accuracy of information.

Question. What is CDC doing about paid advertising? Is the AIDS Hotline system serving the needs of the public?

Answer. CDC, at the direction of the Assistant Secretary for Health, is conducting a feasibility study to assess the effectiveness of paid in-home and out-of-home advertising concerning HIV prevention directed toward hard to reach audiences (Minorities, youth, the underserved, non-English speaking). The report, expected in September 1990, will provide: a range of evaluation options including determining the effect of paid advertising on total airtime, a set of comparable communities which could serve as the study sites, information regarding media access at these sites; a discussion of monetary, personnel, and time costs of an adequate study.

The National AIDS Hotline is meeting the public's information needs by providing services in English, Spanish, and for the hearing impaired. The system currently averages 1.3 million calls annually.

Question. How is the AIDS Information Clearinghouse meeting the information needs of the health professionals and the public?

Answer. The National AIDS Information Clearinghouse (NAIC) was established to serve the general public through health professionals and other health intermediaries and in further support of hotline inquiries. The NAIC is working with the National Library of Medicine, Food and Drug Administration, National Institute of Allergy and Infectious Diseases, Health Resources and Services Administration, and the National AIDS Program Office to streamline services to health professionals.

Question. What new services, including the Clinical Trials Information Services, are being offered?

Answer. The best current example is the AIDS Clinical Trials Information Service which is already serving 2,000 calls per month on a toll-free basis. The most recent resource added to the NAIC database is a public and private funding sources listing for HIV prevention and related services.

The National Library of Medicine has adapted the information contained in the trials database for direct searching by endusers along with its family of other AIDS/HIV related databases

NATIONAL VACCINE PROGRAM

Question. What was the budget request and justification originally presented to OMB for the National Vaccine Office?

Answer. The FY 1991 request to OMB was for $16,508,000 and 43 FTEs. The funding request included $15,100,000 and 27 FTEs for the PHS agency vaccine activities and $1,408,000 and 16 FTEs for the National Vaccine Program Office.

The $15,100,000 and 27 FTEs would support the following activities:

Pertussis -- $5,500,000 and 7 FTEs to support a field trial and basic and applied research.

Measles -- $2,000,000 and 4 FTEs for studies to develop rapid diagnostic tests to detect measles virus infection.

Conjugated vaccines -- $2,000,000 and 4 FTEs for additional trials with more potent candidate vaccines and extramural lab research.

Vaccine safety -- $1,500,000 and 1 FTE to monitor the safety of licensed vaccine.

Vaccine evaluation -- $1,000,000 to create a vaccine evaluation unit to continuously evaluate candidate vaccines.

Poliomyelitis -- $2,100,000 and 10 FTEs to carry out polio eradication studies called for by the Institute of Medicine and for expanded efforts in the laboratory.

Serological correlates of protection -- $1,000,000 and 1 FTE for additional research efforts.

Question. What funding level would be necessary to support clinical trials and other activities of the National Vaccine Program in order to make the fastest possible progress on development of improved vaccines.

Answer. Developing safe and effective vaccines is a high priority of the Public Health Service. The FY 1991 funding request of $6,914,000 for the National Vaccine Program is augmented by an additional $7,000,000 requested by the National Institutes of Health, the Food and Drug Administration and the Centers for Disease Control. These funds will support an additional pertussis field trial and basic and applied research to accelerate the development of new candidate pertussis vaccines. At this time, the total funding level of $13,900,000 will fund the highest priority vaccine research and development.

FAMILY PLANNING PROGRAM

Question. The Administration has proposed once again to change the Family Planning program from a federally-administered program to one administered by the States.

-- Under your proposal, how would parents be involved in providing family planning services to teenagers?

Answer. The proposal to change Title X into a state administered family planning program will provide a more effective means of delivering services than the current program. This proposal will create a family planning program with increased flexibility to meet local service needs and priorities. In addition, state administration of family planning will enable better integration of family planning services with related services including prenatal care and maternal and infant health services.

Certain basic requirements of the current program would be retained, including the requirement for priority in serving low-income families, the requirement that acceptance of services be voluntary, encouragement of family participation, and the prohibition on use of Title X funds in programs where abortion is a method of family planning.

Within the framework of these retained requirements, states would have increased flexibility to design programs which conform to state policies and standards on matters such as parental consent or notification for provision of contraceptives to minors.

Question. What role do you see for the Title X program in the support of school-based health clinics?

Answer. The decision about whether or not to support school-based health clinics, particularly those which provide contraceptive services to teens, is clearly one that should be made by the local community involved. The Administration's proposal would neither prevent nor promote use of Title X funds to support school-based clinics. However, by moving the locus of decision about allocation of Title X resources out of the hands of private boards and into the hands of publicly accountable state agencies, this proposal makes it more likely that decisions about school-based clinics will be made with community standards and community preferences in mind.

Question. Please describe the current status of the family planning regulations and the judicial action around them.

Answer. In 1988, three separate lawsuits were filed in the District Courts in Denver, Boston, and New York challenging the regulations on statutory and constitutional grounds. The Department was enjoined from enforcing the regulations by the District Courts in Denver and Boston; the New York court upheld the regulation.

All three cases were appealed. On May 8, 1989, the United States Court of Appeals for the First Circuit (Boston) affirmed the lower court decision striking down the regulations.

The Department requested a rehearing en banc of the First Circuit decision. On August 9, 1989, following the Supreme Court's decision in Webster v. Reproductive Health Services, the First Circuit granted the Department's request for rehearing and vacated its earlier opinion; oral argument was held in December and the case is pending. The permanent injunction entered by the lower court in Boston remains in effect.

On November 1, 1989, the United States Court of Appeals for the Second Circuit affirmed the decision of the New York District Court upholding the regulations. Plaintiffs have obtained a stay of that decision pending appeal to the Supreme Court.

The U.S. Court of Appeals for the Tenth Circuit has not yet ruled on the decision of the Denver District Court, and the permanent injunction entered by that court remains in effect. Thus, the only final appeals court ruling at this time is one from the Second Circuit (New York) upholding the Department's position.

In 1989 a lawsuit was filed by several Title X subgrantees in West Virginia seeking to enjoin implementation of the regulations in that state. A preliminary injunction was issued in the West Virginia case in August, 1989, pending a decision on the merits.

The Department has implemented the regulations as grants have come up for renewal except where enjoined from enforcing the regulations. To date, the regulations are being implemented in Kentucky, Texas, South Dakota, Iowa, part of Nevada and all of the territories.

Question. Since 1983, the Department has failed to collect data or conduct analysis of Title X services despite having submitted a plan to Congress in 1984 that promised to do so. What are the Department's plans for collecting data on the need and the provision of family planning services in FY 91?

Answer. We plan to continue our current data collection activities, the focal point of which is the National Survey of Family Growth (NSFG). Since 1981, the Title X program has provided substantial financial support for the NSFG, which is conducted by the National Center for Health Statistics. The NSFG is widely recognized as the best source of national data on pregnancies, family planning utilization and family planning trends.

In addition Title X grantees continue to participate in the Bureau Common Reporting Requirements (BCRR) which is operated by the Bureau of Health Care Delivery and Assistance (BHCDA). The BCRR system provides information on numbers and characteristics (age and low income status) of persons served in Title X programs.

Family planning need estimates continue to be developed periodically by the Alan Guttmacher Institute (AGI), although without Federal assistance. The most recent date published by AGI were in October 1988 and are generally available to family planning policy makers and administrators.

MINORITY HEALTH RESOURCE CENTER

Question. How is the Minority Health Resource Center publicized, and who is entitled to use this resource?

Answer. In late 1988, OMH-RC staff began efforts to actively promote the services and products available from the Office of Minority Health Resource Center (OMH-RC). To allocate staff time and limited funds, a promotion plan was prepared. In preparing the plan, emphasis was placed on defining the most effective strategies for reaching the Resource Center's primary target audience: professionals. The OMH-RC promotion strategy has focused on using intermediary groups to reach professionals involved with minority health programs and professionals that work with ethnic and racial minority populations. Three key messages have been stressed:

- To create an awareness of the minority health disparity;
- To inform professionals that the OMH-RC is available to help them locate relevant minority health resources; and
- To promote the availability of a nationwide toll-free telephone number for accessing the OMH-RC.

Various mechanisms have been used for disseminating information on the OMH-RC's services and products. Elements of this effort have included an exhibit program, announcements of new products, a series of fact sheets on the health disparity, direct advertising, mailings to update users on new OMH-RC activities, and liaison efforts with relevant organizations. A selection of OMH-RC promotion activities is summarized below:

- Contacted over 350 national, minority, and health-related professional organizations such as the National Urban League, National Medical Association, National Hispanic Nurses Association, American Indian Health Care Association, and the Asian American Health Forum.

- Informed public agencies including relevant Federal offices and programs and each State Health Department.

- Sent information to national information centers and nearly 200 predominantly minority universities and colleges.

- Displayed the OMH-RC exhibit at twenty national conferences across the United States including meetings of the National Coalition Hispanic Health and Human Services Organizations (COSSMHO), the American Public Health Association, and the National Urban League.

- Placed six paid advertisements in professional journals including Health Education and the American Journal of Public Health. These advertisements promoted the availability of the Office of Minority Health Resource Center as a national service that provides assistance in locating minority health resources and information. The intent of these advertisements is to increase public awareness of a new Federal information service regarding minority health issues.

Question. What is the utilization experience of the Office of Minority Health Resource Center -- how many requests for information have been received and responded to?

Answer. The Office of Minority Health Resource Center initiated a toll-free telephone service for responding to public inquiries in April 1988. As of January 1990, the OMH-RC has responded to a total of 6,808 information requests received on local and toll-free telephone lines, by mail, and in person. The majority of these calls have been received via the toll-free telephone line.

Although the toll-free telephone service became available as April 1988, active promotion of this service did not begin until late in 1988. Therefore, during the early months, the call volume remained low. The number of inquiries handled by OMH-RC staff has steadily increased. During the last six months, the monthly average of completed requests has been approximately 416.

COMMISSIONED CORPS

Question. The U.S. Commissioned Corps is sometimes referred to by its critics as the "White Males Club." What is the representation in the U.S. Commissioned Corps of women and minorities?

Answer. The numbers of Public Health Service commissioned officers by gender:

	March 1987		December 1989	
	Number	Percentage	Number	Percentage
Female	1,194	22.3%	1,481	26.1%
Male	4,172	77.7%	4,185	73.9%
TOTAL	5,366		5,666	

Since the advent of the revitalization program of the Commissioned Corps of the Public Health Service in April 1987, there has been a 24 percent increase in the number of female officers.

The numbers of Public Health Service commissioned officers by race/ethnicity:

	March 1987		December 1989	
	Number	Percentage	Number	Percentage
Native American	235	4.4%	321	5.7%
Asian	145	2.7%	171	3.0%
Black	227	4.2%	273	4.8%
Hispanic	122	2.3%	157	2.8%
White	4,516	84.2%	4,709	83.1%
No Data	121	2.3%	35	.6%
TOTAL	5,366		5,666	

Under the commissioned corps revitalization program which began in April 1987, the number of Native American officers has increased 36.6 percent; for Asian officers --- 17.9 percent; for Black officers --- 20.3 percent; for Hispanic officers --- 28.7 percent; and for White officers --- 4.3 percent.

Question. What is the Department doing to recruit more women and minorities into the Corps?

Answer. In April 1987, the Commissioned Corps of the Public Health Service embarked upon a comprehensive revitalization program designed to improve the image, management, utilization, and composition of the corps. As part of this effort, a number of special initiatives were developed to improve the recruitment and retention of women and minorities. For example, recruitment efforts have been targeted to historically Black colleges and to colleges with large numbers of American Indian, Hispanic, and Asian students.

The Commissioned Officers Student Training and Extern Program (COSTEP) provides an opportunity for health professional students to have a work experience in the Public Health Service and to consider the challenge of a professional future with the Public Health Service as a career option. The COSTEP program has been greatly expanded during the past three years to make opportunities available to women and minority students who have an interest in a public health career. For example, in 1986 only 79 females participated in the COSTEP program but, in 1989, the number of women increased to 358, or 55 percent of the participants.

Moreover, in 1989 of the 505 COSTEP participants whose racial/ethnic designation was known, minorities accounted for 25.5 percent. The 505 included: 376 White (74.5 percent); 69

Black (13.7 percent); 25 Asian (5 percent); 24 Native American (5 percent), and 11 Hispanic (2.2 percent). The total number of COSTEP participants in 1989 was 650.

In addition, special committees have been established to provide guidance on recruitment efforts as they relate to Blacks and Hispanics. These activities have contributed to a 26.5 percent increase in the number of minorities in the corps since April 1987. The percentage of minorities in the corps now stands at 16.3 which is up from 13.6 percent when the revitalization effort began in April 1987 and is more than double the percentage of minorities (7.1 percent) in the corps in 1978.

Though substantial improvements have been made in the representation of minorities and women in the commissioned corps, there are still several disciplines within the corps in which they continue to be underrepresented. Efforts are underway to correct these problems primarily by building upon the experiences and successes of the past three years.

USER LIAISON PROGRAM

Question. Dr. Clinton, state legislators make the same critical decisions about health care issues and spending priorities as we do here in Congress. Legislators in my state say the User Liaison program gives them access to vital information about current issues in health care, without which they would have to make decisions without adequate background. How will this program be operated under AHCPR?

Answer. The User Liaison Program currently plays and will continue to play a key role in the program activities of the AHCPR. More specifically, it will continue to ensure that this Agency maintains effective liaison with State and local government policymakers around the country. The Agency's efforts to develop a research agenda which is relevant for State and local government policymakers will be based on meetings conducted by the User Liaison Program at which State legislators, as well as local officials and State executives will provide their views on the subjects which should be addressed by health services research. An active program of workshops is presently being developed for calendar year 1990.

Question. What workshops are planned for this year?

Answer. The following workshops are planned for calendar year 1990:

SUBJECT:	Rural Health Care
AUDIENCE:	Idaho State legislators and executives
DATES:	June 4-6
LOCATION:	to be determined

SUBJECT:	Child Health Care
AUDIENCE:	State legislators, State executives and local government officials
DATES:	June 25-29
LOCATION:	Snowbird Conference Center, outside Salt Lake City, Utah

SUBJECT: Rural Health Care
AUDIENCE: State and local legislators and executives from Mississippi, Alabama, Florida, Georgia, South Carolina and Tennessee
DATES: July 9-13
LOCATION: to be determined

SUBJECT: Medical Effectiveness Research
AUDIENCE: State legislators, State executives and local government officials
DATES: August 20-24
LOCATION: Rensselaerville Institute, just outside Albany, New York

SUBJECT: AIDS
AUDIENCE: State legislators, State executives and local government officials
DATES: October 15-19
LOCATION: The Rensselaerville Institute

A workshop dealing with some aspect of minority health care issues is tentatively planned for September 9-13. A workshop concentrating on health care issues of prime concern to local government officials, i.e., elected county officials, county-city health officers and mayors is tentatively scheduled to be held at the Port Ludlow Conference Center in the State of Washington November 26.

Question. What is your FY 1991 budget request for this program and how many workshops would be funded?

Answer. The budget request for the upcoming fiscal year, 1991, is $1,058,000. It is anticipated that these funds will support between seven and nine workshops.

MEDTEP COORDINATION WITH STATES

Question. How is the Agency working to coordinate work on medical treatment effectiveness with state programs and initiatives?

Answer. The User Liaison Program is working with a select group of State officials and knowledgeable researchers to develop recommendations as to how MEDTEP activities can reflect the needs of State governments. This group is currently addressing the question of data development. In addition, a workshop is being developed in collaboration with current and former state officials that will provide information to an audience of State and local government officials regarding the nature of the medical effectiveness issue and the importance of past and on-going medical effectiveness research.

DRUG TREATMENT EFFECTIVENESS

Question. Does the Agency for Health Care Policy and Research have a role in the Administration's war on drugs?

Answer. The Agency for Health Care Policy and Research (AHCPR) does not have a direct role in the Administration's war on drugs. However, to the extent that AHCPR-sponsored research findings regarding the structure, processes, and outcomes of health care can be helpful to this war, the wide and timely dissemination of these findings may assist those agencies that are directly involved in studying or reducing drug abuse.

Question. Does the Agency have the capacity to evaluate different methods of drug treatment?

Answer. The Agency for Health Care Policy and Research (AHCPR) is prepared to provide technical assistance to the National Institute on Drug Abuse in their ongoing efforts to evaluate different methods of drug treatment related to drug abuse. The AHCPR does not have the capacity to undertake independently these evaluations.

However, P.L. 101-239 authorizes the AHCPR to sponsor new studies on the appropriate use of prescription drugs. AHCPR's capacity to carry out the evaluation of drug treatment is demonstrated by its long-time support for research on the appropriate use of drug treatment. For example:

- Schaffner and Ray at Vanderbilt University have shown that a non-punitive, educational program sponsored by the medical profession and consisting of single, brief office visits by physician counselors was highly successful in reducing prescriptions of contraindicated antibiotics and in the substitution of more economical, but equally effective, alternatives to oral cephalosporins.
- Avorn and Soumerai at Harvard demonstrated that a face-to-face "detailing" program which utilized clinical pharmacists achieved a significant decrease in inappropriate prescribing of three target groups by office-based physicians.
- Gardner at Latter Day Saints Hospital showed that computer feedback on inappropriate and unnecessary use of antibiotics was effective in improving physicians' drug prescribing behavior.
- Showstack at the University of California showed that use of the immunosuppressive drug cyclosporine, which reduces graft rejection, may significantly reduce treatment costs for patients who received donated kidneys from cadavers.

COORDINATION OF RESEARCH EFFORTS

Question. How will AHCPR coordinate effectiveness research with HCFA, NIH, CDC, and other agencies in the Public Health Service?

Answer. The Medical Treatment Effectiveness Program (MEDTEP) involves a multifaceted approach to address complex issues of health care delivery. Research initiatives will incorporate the complementary efforts and unique strengths of the Agency for Health Care Policy and Research (AHCPR), other agencies of the Public Health Service, and the Health Care Financing Administration (HCFA).

- An Intra-Departmental Coordinating Committee has been created to ensure full collaboration among HCFA, PHS, the Assistant Secretary for Planning and Evaluation, and the Assistant Secretary for Management and Budget.

- HCFA's role will include:
  - -- linking, standardizing, and improving Medicare and Medicaid data bases;
  - -- adding supplemental measures of health status to existing data; and
  - -- generating special data sets for studies on specific subpopulations of program beneficiaries.
- Within the PHS:
  - -- The Health Resources and Services Administration (HRSA) will assist in the adoption of medical effectiveness research findings into clinical practice, through HRSA's long-standing support of health professions education and curriculum development, and its historic ties to State licensing bodies.
  - -- The Centers for Disease Control and the National Institutes of Health are bringing to AHCPR's attention new areas of inquiry related to patient outcomes research, for discussion and possible funding support.
  - -- A PHS Coordinating Committee for MEDTEP has been created to facilitate full involvement of PHS agencies.

Question. What medical, nursing, allied health, rural health, and other organizations are involved in the MEDTEP initiative?

Answer. The Agency for Health Care Policy and Research (AHCPR) will continue its concerted effort to involve a wide range of health care professional groups and other private organizations in the development of initiatives under the Medical Treatment Effectiveness Program (MEDTEP). This includes ongoing discussions with all concerned parties with respect to the development of guidelines, the conduct and support of research, and the development of data bases.

Specifically, the AHCPR will benefit from its interaction with other Federal agencies, members of the research community, and professional organizations with respect to:

- collaborative development of clinical guidelines;
- development of a 5-year MEDTEP research agenda;
- workshops on MEDTEP for State and local representatives;
- advice to be provided by a National Advisory Council for Health Care Policy, Research, and Evaluation, which includes a Subcouncil on Outcomes and Guidelines; and
- availability of data appropriate for outcomes research.

RURAL HEALTH CARE PROVIDERS

Question. There are two notable differences between rural health providers and practitioners in urban areas. Rural health providers tend to be generalists as opposed to specialists; and they are often isolated from others in their profession. This makes them vulnerable to falling behind the latest medical practices especially solo practitioners in isolated areas. How will you reach providers with your findings?

Answer. Several strategies are presently being formulated. Some will rely on normal medical channels of keeping practitioners informed about advances in the field. Others will seek to develop innovative ways to reach isolated providers. For example, we have just started a monthly column in Journal of the American Medical Association (JAMA) to highlight the findings of patient outcome research, guideline development activities, and other AHCPR-funded research that affects practitioners. Such mechanisms will bring increased visibility of AHCPR research findings to professional groups and specialties who might not be reached by traditional means.

It presently is unclear how isolated practitioners update their professional knowledge and skills. For example, do they attend medical society meetings? What journals do they receive and which articles do they read? What do they learn from their colleagues? The answers to such questions are important and we will develop research to assist us in understanding the dimensions of those questions and their impact on medical practice.

Question. How will AHCPR coordinate its dissemination of information with the National Library of Medicine's outreach program to rural health practitioners?

Answer. AHCPR is working closely with the National Library of Medicine (NLM) to improve the dissemination of health services research, medical treatment effectiveness research, and practice guidelines to all practitioners. NLM's online system and its Regional Medical Library (RML) network will provide the necessary infrastructure for expanding and enhancing services in these areas.

With respect to rural practitioners, key staff have been identified from both AHCPR and NLM agencies to assist in the process. Working groups will be formed to develop techniques and mechanisms tailored to meet the unique information needs of rural practitioners.

AHCPR and NLM will ensure that these mechanisms are introduced to rural health care providers through the special outreach initiatives directed by the Regional Medical Libraries and carried out with the assistance of about 4,000 hospital and other health sciences libraries in the RML network. Through user-friendly connections to NLM's online databases and to the document delivery service provided by RML network libraries, isolated providers can have effective access to the results of health services research, medical treatment effectiveness research, and to the practice guidelines based on this research.

NATIONAL MEDICAL EXPENDITURE SURVEY

Question. What are recent findings from the National Medical Expenditures Survey on the uninsured?

Answer. Data from the 1987 National Medical Expenditure Survey (NMES), conducted by the Agency for Health Care Policy and Research have provided information on the uninsured population. Data have revealed that:

- 37 million Americans, or 15.5 percent of the U.S. population, were without private or public health insurance in the first quarter of 1987;
- This estimate represents a substantial growth in the number of uninsured persons since the first quarter of 1977, when 26 million persons or 12.3 percent of the U.S. population was uninsured;
- About half of all uninsured persons are workers and together with their dependents represent over three-quarters of the uninsured;
- The working uninsured tend to be concentrated in small firms, with two-thirds of uninsured workers in establishments with 25 or fewer employees;
- Low wage workers earning $5.00 per hour or less and those employed in industries characterized by seasonal or temporary employment and a less technically skilled workforce (such as agriculture, construction, sales, repair, business services, and personal services) are most likely to be uninsured;
- Black and Hispanic persons are twice as likely as whites to be uninsured; and
- Over a third of the uninsured are either poor or near-poor, with family incomes less than 125 percent of the federal poverty line.

AIDS

Question. NCHSR recently awarded a contract for the study of the costs and utilization of HIV-related health care services. When will the study be complete, and what are the goals of the study?

Answer. NCHSR awarded a three year contract to Westat, Inc. for the study of the costs and utilization of HIV-related health care services on September 25, 1989 (AIDS Cost and Service and Utilization Survey (ACSUS). The goal of this contract is to provide policy-relevant data on the HIV epidemic that exceeds the scope of any currently available. Data will be obtained on the financial resources required to treat people with HIV and the sources of payment. Information on the utilization and costs of all health-related services including all out-of-pocket expenses (e.g. outpatient drug costs) and volunteer services will be collected. In addition, data on social, mental and oral health services, informal social support systems, barriers to access, quality of life, and employment history will be obtained.

ACSUS will collect uniform data from a national sample of persons with AIDS and other HIV-related illnesses. The survey will begin in October 1990 and will include information from approximately 1500 adults and adolescents and 100 children. The sample will be followed for 18 months and interviews will be conducted every three months in an effort to limit recall bias. At the time of enrollment in the study, approximately half the sample will have a diagnosis of AIDS, and half will be HIV-positive but without AIDS. The sample will be drawn from at least 8 cities around the Nation.

PLAN FOR EFFECTIVENESS RESEARCH

Question. The Committee provided funds in Fiscal Year 1990 for a conference to develop a five-year plan for the medical treatment effectiveness initiative. When can we expect to see the five-year plan?

Answer. The Agency for Health Care Policy and Research (AHCPR) has developed a scope of work and has produced a competitive Request for Contract for a Medical Treatment Effectiveness Research Agenda Development Conference. Federal procurement rules prohibit distribution of the scope of work at this time. The period of performance for this procurement was planned to begin on or about May 15, 1990. Procurement procedures resulted in our withdrawing the contract procurement to reassess more appropriate means to meet the Committee's objectives. We will provide an update of this action by June 30.

The results of this conference (combined with the recommendations of AHCPR's newly mandated National Advisory Council for Health Care Policy, Research, and Evaluation; the Intra-Departmental Committee on Medical Treatment Effectiveness; and the PHS committee for the Medical Treatment Effectiveness Program) will form the basis for AHCPR's five-year plan.

Question. Will effectiveness research also include mental health?

Answer. Yes, the Agency for Health Care Policy and Research (AHCPR) expects to sponsor medical effectiveness/patient outcomes research or guideline development dealing with the use of health care services and procedures in mental health. This expectation is based on our collaboration with the National Institute of Mental Health (and other agencies represented on the PHS committee for the Medical Treatment Effectiveness Program--MEDTEP) in determining priorities for research and guidelines carried out by the MEDTEP.

EFFECTIVENESS RESEARCH BUDGET

Question. Please give an accounting of expenditures for the outcomes effectiveness activities of the Department in FY90. How are these funds to be spent?

Answer. In FY 1990, of the $37.5 million available for the Medical Treatment Effectiveness Program (MEDTEP), $27 million was appropriated and $5 million was transferred from the Medicare Trust Funds. Pursuant to Public Law 101-166 the appropriation was reduced by $162,000. An additional $5.7 million is available from evaluation funds, pursuant to section 926(b) of the Public Health Service Act. These funds will be spent on the following activities: Research and data development - $34.7 million; Guidelines - $1.8 million; and Dissemination - $1 million.

Question. How are AHCPR's funds to be distributed in FY90 and FY91 among the three areas of activity: research, data development, and dissemination?

Answer. The funds will be distributed in the following manner:

(dollars in millions)

	1990	1991
Research	$28.3	$34.1
Data Development	6.4	9.1
Dissemination	1.0	2.7
Guidelines	1.8	2.6
Total	$37.5	$48.5

RURAL HEALTH RESEARCH

Question. Please provide the Subcommittee with a detailed accounting of expenditures for the rural health research agenda for FY88-90.

Answer. Expenditures for the rural health research agenda for FY 88-90 are as follows:

Rural Health Research
($000)

	1988	1989	1990
Budget Authority	$300	$500	$1,236
1% Eval Funds	0	179	1,253
Total	$300	$679	$2,489

In FY 1988, the NCHSR awarded a grant to support a Congressionally mandated conference organized by the National Rural Health Care Association and the Foundation for Health Services Research to develop an agenda for health services research on rural health care problems. HCFA and the Kaiser Family Foundation also invested financially in this conference. The conference brought together over 150 participants which included a mix of rural providers, rural health services professionals, policy makers, and health services researchers. The proceedings of the conference were published in Health Services Research as a special February 1989 issue. The five cross cutting issues identified were:
health status; access and utilization; financing; delivery system and organization; and health professions and manpower.

The six stimulus papers were: problems of the rural elderly; issues in long term care; the rural poor and medically indigent; maternal, child and adolescent health; the future of the rural hospital; and primary care and alternate delivery systems.

In FY 1989, $500,000 was appropriated to NCHSR to begin research on the rural health services research agenda developed during this conference. To stimulate extramural research applications on rural health issues, the NCHSR Program Note, "The Role of Market Forces in the Delivery of Health Care: Issues for Research," identified several areas for investigator-initiated research on the costs and financing of rural health care as recommended by the conference participants.

In FY 1989, the former NCHSR funded four new extramural grants with the $500,000 directly appropriated to NCHSR for rural health care research. All four will be continued in FY 1990 by AHCPR. Topics include:

-- Why rural Maine residents using federally-funded community health centers have lower rates of hospitalization than non-CHC users;

-- The barriers to access to health care faced by the rural uninsured and medically indigent in Nebraska;

-- The types of alternative health services that the rural elderly, rural poor and rural Blacks use, either because of access barriers to traditional health care services or the availability of alternatives; and

-- Urban/rural differences in survival rates and utilization of health and community-based services by the elderly.

In addition, in FY 1989 we funded one ongoing project and one new project out of evaluation funds totalling $179,000 that examine rural health care issues:

-- The relative effectiveness of various management strategies by rural hospitals to identify the most successful strategies;

-- Variations in resource use, costs and outcomes among rural and urban obstetricians, family practitioners and nurse midwives in Washington State.

In FY 1990 and 1991, AHCPR will spend $2.5 million on rural health care. The AHCPR plans to fund additional new grants dealing with rural health care issues (some of which may be jointly funded in FY 1990 with the National Center for Nursing Research).

For example, we will be funding a grant to a rural researcher who has established a reputation as a leader in the field of prevention. He will be testing ways to improve the frequency with which physicians provide health promotion/disease prevention services to their patients. Two of the three test sites are in Appalachia. The agency will also support a study to improve health and reduce health care costs for children of low-income families in rural areas by increasing utilization of Early and Periodic Screening, Diagnosis and Treatment (EPSDT), a Federal program providing comprehensive health promotion/disease prevention services for Medicaid-eligible individuals from birth to age 21.

-- The AHCPR's intramural Hospital Studies Program will soon release information on the most frequent diagnosis and procedures performed in small and large, rural and urban hospitals. These statistics allow urban-rural comparisons on hospital charges and lengths of stay, types of patients, death rates, and typical payers for hospital services for the fifty most frequent procedures, diseases, and DRGs found in these hospitals.

- -- This same research program is studying financial distress among U.S. hospitals in the 1980s -- one dimension will explore differences in financial viability between rural areas with low population density and other rural and urban areas.

- -- On February 9, AHCPR, through its User Liaison Program, convened a meeting of rural researchers, and county, State, and Federal policymakers to gain their views on new research that would be valuable to them as they address rural health care issues.

In total, $2.5 million will be devoted to rural health activities in FY 1990, $1.2 million from budget authority and $1.3 million from PHS evaluation funds.

Technical Assistance

Staff of AHCPR are finalizing plans with the Office of Rural Health Policy to develop three types of programs of technical assistance.

- o First, we will provide technical assistance to the five rural research centers funded in the HRSA budget.
- o Second, the User Liaison Program has scheduled technical assistance activities for the States of Idaho and Alabama (and possibly Vermont and North Dakota) pertaining to aspects of rural health care.
- o Third, we will conduct public technical assistance workshops open to all rural researchers.
  - -- Initially, we will schedule sessions at the five rural research centers and at the National Rural Health Association meeting this May.
  - -- In the future, we intend to schedule sessions in areas that are not near existing rural research center sites.

One of the goals of these workshops for rural health researchers and rural institutions is to improve their capacity to develop scientifically sound research proposals.

HOSPITAL STUDIES

Question. What was your budget request and justification to PHS and to OMB for the NMES and Hospital Studies Program in FY91?

Answer. The FY 1991 budget request to PHS for the NMES and Hospital Studies Program was $13,757,000. The request to OMB was the same. Both the NMES project and the Hospital Studies Program are designed to provide policy research and analysis to the Federal government. Data and analysis from these activities have been used by various agencies in DHHS, the Department of Veterans Affairs, the Department of Treasury, OMB, and the Congressional Budget Office as well as congressional committees. Based on the value of the data assembled by AHCPR and the policy research and technical assistance based on these data, the administration has proposed continued support for these projects. The President's Budget reflects the level of support required for these activities.

ORPHAN DRUG ACT

Question. We understand that there is some interest in an amendment to the Orphan Drug Act to permit a different regimen for aerosol pentamidine, which was developed at Memorial Sloan-Kettering and which might prove more cost-effective and more convenient for the patient. Will the Administration support such an amendment so that people with AIDS can have as many treatment alternatives as soon as possible and can obtain this important therapy more inexpensively?

Answer. We are not aware of any such amendment as mentioned being contemplated to the Orphan Drug Act. The Orphan Drug Act does not deal with the regimen of how a specific drug is given. Rather the Act is designed to assist in the development of products for a specific rare indication, e.g. treatment of Pneumocystis pneumonia, or prevention of Pneumocystis pneumonia. This Act in no way deals with whether that product is given via mouth or aerosolized or via injection. It could be given in any of those ways. The important point is the indication for which it is given.

GENERAL HEALTH SERVICES RESEARCH AREAS

Question. Outside of effectiveness research there are many other problems which health services research should address. They include: access for rural areas and low income and minority households to health care; lack of universal health insurance; the future of small rural hospitals; and increasing productivity of health care. What steps are you taking to address these and other health services research issues?

Answer. We have a twenty year history of studies across the board in health services research and currently maintain a large ongoing program of projects other than effectiveness studies.

However, to announce our new status as an agency and to further direct investigators looking for funding, we are in the process of reissuing program notes which describe the research we are doing and the research we would like to address thereby encouraging investigators to submit applications responsive to the general statements in the program notes. The Center for General Health Services Extramural Research is comprised of four subareas which address the a multitude of research areas:

- Technology Assessment
    - Assessments of Specific Technologies
    - Technology Assessment Methods
    - Medical Decision Making
    - Information Systems
    - Database Development

- Organization and Financing of Care
    - Costs, Cost containment
    - Cost Benefit/Cost Effectiveness
    - Economic Models
    - Organizational Models

Licensure and Regulation
Medical Liability

Measures of Quality
Personal Responsibility
Physician Patterns of Practice
Patient Compliance
Preventive Services
Measures of Outcome
Medical Malpractice
Health Promotion/Disease Prevention

Service Delivery Systems
Minority Health
Rural Health/Underserved
Long Term Care
AIDS
Home Care
Dental Care
Primary Care

One half of our FY 1990 grant and contract budget is being used to fund other than effectiveness studies.

TRAINING HEALTH SERVICES RESEARCHERS

Question. In the past, NCHSR has funded training programs for health services research. Given the increased interest in this area does the Department have any plans to reinvigorate this program?

Answer. Our current efforts toward training health services researchers are being accomplished through the National Research Service Awards (NRSA) program and a dissertation research program. We have been awarding NRSA grants since FY 1986. Currently there are ten NRSA awards to the following institutions: The Rand Corporation; University of Pennsylvania; University of California at Berkeley; Harvard University; Stanford University; Brown University; Johns Hopkins University; University of North Carolina; University of Washington; and, the University of Minnesota. These institutions have trained or are training a total of 74 students, including 34 M.D.s, 14 Ph.D.s and 3 dentists. During this same period, 21 individual awards were made. Fifteen of the trainees are M.D.s and the remaining six are Ph.D.s.

NCHSR began awarding dissertation grants in FY 1976. In 1982, due to severe budget cuts we were not able to award any dissertation grants. From FY 1976 through FY 1989, we have awarded 152 dissertation grants; many of these researchers have developed into outstanding contributors to health services research, many have published in refereed journals.

We are currently resurrecting an additional training opportunity that we used several years ago--supplementing existing grants whose principal investigator accepts the challenge of training a new health services researcher.

Lastly, we have set aside $1 million of our MEDTEP funds to train researchers in the skills necessary to do effectiveness research. These funds will be competed for by our large effectiveness program grants.

REORGANIZATION OF FAMILY PLANNING

Question. Dr. Mason, the Committee is concerned about proposals to reorganize the Public Health Service regional offices and the impact reorganization would have on the Family Planning program. Family planning clinics prefer to keep the current process of funding through the PHS regional offices, and the Congress prefers to keep the process intact also. As you know, both House and Senate Subcommittees directed that we be consulted prior to any reorganization of these offices.

-- What is the Department's current position on this issue: are you taking steps to reorganize or otherwise change the administrative process for funding Title X services?

Answer. Legislative action directing that administration and management of many of the Health Resources and Services Administrations's grant programs be taken from the Regional Offices and returned to the agency's Bureau of Health Care and Delivery Assistance required examination of the feasibility of keeping the few remaining grant programs operating through the Regional Offices. Discussions are continuing as to the advisability of returning all grant programs currently administered in the regions back to the individual programs. I want to assure you that if we do decide to modify the operation of the PHS regional offices, we will comply with the Conference Report on the 1990 Labor-HHS Appropriations Bill before proceeding with a regional office reorganization.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

NATIONAL VACCINE PROGRAM

Question. The FY 90 appropriation for the National Vaccine Program included funds to establish an office for the program and to coordinate pertussis vaccine research and clinical testing. What progress has been made in hiring staff for the National Vaccine Program and establishing the office?

Answer. After an extensive search, Dr. Kenneth Bart has recently been appointed as the full-time National Vaccine Program (NVP) Deputy Director replacing Dr. Alan Hinman who served as the NVP Coordinator on a part-time basis.

The NVP is in the process of hiring the necessary staff to fully comply with the legislative requirements to "coordinate and provide direction for all vaccine related activities in the Federal Government" within the FTEs allocated.

There are currently five full-time persons in the National Vaccine Program Office, including the Deputy Director, a Scientist Administrator, a Program Analyst and two Secretaries. As qualified candidates are identified they will be added to the National Vaccine Program Office staff.

The NVPO is also providing FTEs to the Centers for Disease Control (CDC), the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) to carry out important vaccine related activities.

Question. In order to plan for pertussis research and trials in FY 91, the subcommittee needs a complete report on the coordination of pertussis trials in FY 90, including information on the status of phase I and phase II trials.

Answer. In FY 1990, the National Institute for Allergy and Infectious Diseases (NIAID) will carry out the pertussis vaccine trials. NIAID will initially evaluate candidate acellular pertussis vaccines in their six Vaccine Evaluation Units (VEUs). Funding for the VEUs will be increased to fund phase I and phase II clinical trials of candidate acellular vaccines. A total of eight new products produced by U.S. and Japanese manufacturers are to be tested for safety and immunogenicity. The results of these trials will be critical to selection of the most appropriate vaccine(s) for the full-scale efficacy field trial which will directly compare the new preparation against the current recommended whole-cell vaccine.

Additionally, NVP will provide resources to CDC, FDA and NIH to carry out the basic and applied research related to pertussis vaccine to elucidate the mechanisms of pathogenesis, identify candidate antigens, provide improved diagnostic methods, and describe the development of immunity to pertussis.

Question. What was your original budget request for the National Vaccine Program? What activities would have been supported by that funding level?

Answer. The original FY 1991 budget request for the National Vaccine Program was $29,205,000 and 62 FTEs. The funding request included $27,500,000 and 44 FTEs for the PHS agency vaccine activities and $1,705,000 and 18 FTEs for the National Vaccine Program Office.

The $29,205,000 and 62 FTEs would have supported the following activities:

National Vaccine Program Office (NVPO) Planning, direction, coordination, advisory committee and support activities ($1,705,000 and 18 FTEs

PHS Agency Vaccine Activities:

Pertussis Vaccines $8,500,000 and 7 FTEs to support 2 new field trials and basic and applied research to accelerate the development of new candidate vaccines (CDC, FDA, NIH)

Measles Vaccine $2,000,000 and 4 FTEs for studies to develop rapid diagnostic tests to detect measles virus infection and assess vaccine-induced immunity (CDC)

Conjugated Vaccines $3,000,000 and 5 FTEs for additional trials with more potent candidate vaccines and laboratory research (FDA, NIH)

Vaccine Safety $1,500,000 and 1 FTE to monitor the safety of licensed vaccines (CDC)

Vaccine Evaluation $1,000,000 to create a new vaccine evaluation unit to continuously evaluate candidate vaccines (NIH)

Poliomyelitis $2,800,000 and 13 FTEs to support polio eradication studies called for by the Institute of Medicine and expansion of current efforts in the laboratory (CDC, FDA)

Serological Correlates of Protection $3,700,000 and 2 FTEs for additional research efforts (FDA, NIH)

Tuberculosis $5,000,000 and 12 FTEs to develop techniques for providing quicker identification of the infection which will impact on the speed of intervention and consequently on the transmission of the disease (CDC, NIH)

QUESTIONS SUBMITTED BY SENATOR WARREN RUDMAN

MEDICAL EFFECTIVENESS TREATMENT

Question. Last year's Budget Reconciliation Act established the Agency for Health Care Policy and Research as the focus of medical effectiveness research (outcomes assessments), medical practice guideline development and information dissemination. The FY 91 budget of $49 million for medical effectiveness includes $16.3 million for new research grants. This request represents a decrease of $3.2 million for new grants from the FY 90 appropriated level. Why are you proposing a decrease in new grants?

Answer. The total requested for research grants is $30.3 million, an increase of $5.8 million over FY 1990 or a 24 percent increase. Many of the grants funded in FY 1990 are multiyear and will be continued in FY 1991. The 1991 budget will continue 28 grants at $13.95 million.

Question. A year ago, the fiscal year 1990 budget requested $52 million for outcomes research and the Administration advocated increasing that amount to $85 million for FY 91. Does this year's budget request of $49 million reflect diminishing support within the Administration for this important new research effort?

Answer. The President's FY 1991 Budget request for outcomes research of $49 million is an increase of 29 percent over 1990. This is a significant increase which fully supports our long-term commitment toward improving the quality of medical care and reducing unnecessary treatments. The FY 1990 appropriation level of $32 million for outcomes research reflects Congressional action. For FY 1990, the final Congressional action on the MEDTEP budget was lower than the Administration's request by $20 million. The final FY 1991 request reflects a reduced financial commitment base (resulting from a lower FY 1990 level) rather than a reduced commitment to the importance of the program.

Question. Your justification indicates that a long-term agenda for medical effectiveness research will be crafted at a conference of both clinical and social scientists to be held in early FY 1991, which will shape the direction of outcomes research and form the basis for new grant and contract research activity. Have you awarded research grants with the FY 1990 monies which were appropriated? Do you anticipate that future research strategies will differ from the ongoing research in this field?

Answer. The Agency for Health Care Policy and Research (AHCPR) has awarded several new grants under the Medical Treatment Effectiveness Program (MEDTEP) with FY 1990 funds. These include one new Patient Outcome Research Team (PORT), that is evaluating practice variations in knee replacement, and support for the continuation of 4 other PORTs evaluating alternative treatments for cataracts, lower back pain, heart attack, and prostate gland enlargement. It is expected that an additional 5-10 new PORTs will be awarded subsequent to scientific approval by peer review panels in February and June of 1990. In addition to new grants on methodologic issues important to medical treatment effectiveness research, it is anticipated that some contracts will be awarded to support research on dissemination, data base development, and health issues pertinent to minority population groups.

FY 1990 monies will support a conference to assist AHCPR in the development of a 5-year research agenda for MEDTEP. This agenda will help to prioritize and define research issues and topics raised in the authorizing legislation and to anticipate emerging research issues. The basic strategy to develop and disseminate scientific information about the effectiveness and appropriateness of the use of health care services and procedures will continue to apply to whatever specific topics are included in the agenda.

Question. At what point in time do you anticipate being able to begin dissemination of outcomes research findings to health practitioners and training institutions?

Answer. Dissemination of outcomes research findings is underway using several mechanisms. Direct announcement of findings is being done monthly through an AHCPR publication that reaches 30,000 people, including targeted specialties and journals. Announcement and dissemination of AHCPR research also continues on a routine basis through the Commerce Department's National Technical Information Service.

Direct distribution of targeted findings through individual AHCPR publications will continue. This will include direct mailings using the AHCPR mailing list, direct mailing using purchased lists from relevant specialties and organizations, and distribution through exhibits at several dozen professional meetings each year.

AHCPR also has arranged selected announcement and publication of findings by professional journals. For example, we now have a monthly column in the Journal for American Medical Association (JAMA) to highlight results of patient outcome research, guideline development, and other research of interest to physicians. We are arranging for announcement or publication in key nursing journals of recommendations on nursing guideline development created through a recently convened ad hoc advisory committee of nurse clinicians, educators, and policymakers.

AHCPR plans to reach the medical educational community through several mechanisms. We have entered into interagency agreements with the Health Resources and Services Administration (HRSA) to enhance research dissemination and assimilation in that agency's health professions training programs.

CENTERS FOR DISEASE CONTROL

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

FARM HEALTH AND SAFETY

Question. Dr. Dowdle, in an effort to begin to address farm health and safety problems, $11.8 million was provided in FY 1990 for a comprehensive agricultural safety and health initiative -- something that has not been done before. Agriculture has been a relatively neglected industry with respect to occupational health and safety. While only 2 percent of the workforce is employed in agriculture, it ranks 2nd in the number of work-related fatalities resulting from traumatic injuries, second in the number of occupational respiratory diseases and first in the number of occupational skin disorders.

Today, I want to discuss with you, what is being done and what more needs to be done and what more needs to be done in farm health and safety. We funded initiatives in surveillance, research, intervention and training.

Dr. Dowdle, would you please tell me where we stand on implementing these new initiatives?

Answer. The National Institute for Occupational Safety and Health (NIOSH) is developing a coordinated program of surveillance, research, and prevention activities. We are preparing to announce the availability of grants and cooperative agreements, hiring personnel, and developing project protocols to implement this program, covering the following activities:

SURVEILLANCE:

Farm Family Health and Hazard Survey: Surveillance data will be collected to determine to which hazards agricultural workers and their families are potentially exposed, the circumstances of exposures, and the health status of these workers and their families. This effort will be administered through cooperative agreements with States, awarding 3-5 in FY 1990.

Public Health Nurses in Rural Communities: Nurses in 30 - 50 rural hospitals nationwide will be funded to: work with County Extension agents and rural families to promote safety and health; report agriculture-related disease and injury cases to the States and NIOSH; provide safety and health instruction in high schools and vocational agriculture schools; and assist county and State Health Departments in surveillance and hazard evaluation.

Injury Surveillance: NIOSH is expanding the "Traumatic Injury Surveillance of Farmers" (TISF) project, which will be a mail survey, conducted in conjunction with land grant universities, to obtain national and State disability prevalence, injury incidence, and exposure information. Complementing TISF, CDC, through a special supplement to the Health Interview Survey, will obtain information to estimate the total number of injuries related to agricultural work occurring among workers and their family members.

RESEARCH:

Agricultural Centers: NIOSH will support the establishment of Centers for agricultural safety and health at sites across the country. They will conduct research, develop model educational programs, develop model prevention programs, assist and evaluate prevention programs implemented by the Agricultural Health Promotion System and others, devise and evaluate engineering and ergonomic technology, and provide consultation. In FY 1990, 2-4 Centers will be established.

Lung Disease Research: Laboratory and field research related to adverse respiratory effects from selected agricultural dusts will be conducted.

INTERVENTION:

Agricultural Health Promotion System: NIOSH will be collaborating with the Department of Agriculture and the Association of Schools of Public Health to establish agricultural injury and disease prevention programs at each of the land grant universities. These universities will in turn work with county extension officers and the cooperative extension program to disseminate information and conduct prevention programs among agricultural workers and their families. The information and prevention programs will be developed by CDC, the Agricultural Centers, State agencies, and other parties.

Cancer Screening: NIOSH will support demonstration projects for prevention, early detection, and treatment of cancer among farmers.

In the fall of 1990, we will also be supporting a Surgeon General Conference in Des Moines, Iowa, to build coalitions, disseminate information, and encourage action to prevent injury and disease in rural areas.

Question. When can we expect to begin to see some results?

Answer. Our various surveillance and intervention activities, which will be in place this fall, should begin immediately to effect health and safety conditions. It will be several years before these activities are operating in full scale, but from the beginning we will be getting health and safety information into the hands of farmers, their families, and into the hands of others in position to assist these rural populations. At the same time, we will be conducting research to improve the effectiveness of recommendations and technology for preventing agriculture-related injury and disease.

It will take several years to develop good information to document our progress because of limitations of current State and national data sources. These data sources are sufficient to know the safety and health problems in agriculture are severe relative to most industries, but we will need the results of the new surveillance activities over the next year to develop reliable baselines for agriculture-related disease and injuries.

FARM FATALITIES/CHILDREN

Question. The National Coalition for Agricultural Safety and Health reports that approximately 300 children are killed each year while engaged in farm-related activities. We do not currently have any outreach in the school system relating to farm safety.

Dr. Dowdle, do you think that such an outreach would be beneficial?

Answer. Yes, children could and should be taught to recognize and avoid hazards on the farm.

Question. Would CDC be in a position to work with the Agriculture Extension Service, local health and education agencies, to develop an outreach program for children?

Answer. CDC plans to promote safety and health education of children through several activities CDC is supporting: Centers for Agricultural Safety and Health that will be developing model educational programs for farmers and their families; an Agricultural Health Promotion System at the land/grant universities which will disseminate information and conduct prevention programs, through the agricultural extension service, to agricultural workers and their families; public health nurses at rural hospitals who will be providing safety and health instruction at local schools; and the Surgeon General's Conference this fall which will be addressing the safety and health of children in agricultural communities and organizations with an interest in this area.

Question. Would you look into this possibility, and provide your analysis of what needs to be done in this area?

Answer. The CDC programs, once they are fully implemented, have great promise for addressing the hazardous safety and health conditions existing in agriculture today.

FARM KIDS/BIRTH DEFECTS

Question. It is my understanding that birth defects are the leading cause of infant mortality in rural states, and that studies have shown an association between those birth defects and the chemicals used in farming.

What is CDC doing to address this problem?

Answer. Birth defects are the leading cause of infant mortality in the United States, not only in rural areas. There is concern that some chemicals used in agriculture may have the potential to cause birth defects -- research is needed in this area. To this end, CDC is providing technical assistance and/or funding for State-based surveillance of birth defects in Washington, California, and New Jersey; and conducting research on biomarkers to develop objective measures of exposure needed to evaluate the relationship between exposure to agricultural chemicals and birth defects and other health effects.

Question. What more needs to be done?

Answer. There are always more scientific opportunities than resources to support them. If additional funds were available, surveillance could be expanded to include more rural States. In addition to developing objective methods of measuring exposures to chemicals, research is needed to evaluate the range of human susceptibility to chemicals. This would ensure that recommendations to protect agricultural workers and their families will be protective for those who are genetically most susceptible to the effects of hazardous exposures.

FARM SAFETY/INITIATIVES IN FY 1991

Question. Dr. Dowdle, I think that we have made a good start in the area of farm health and safety. What are your recommendations for what we should be doing in FY 1991?

Answer. In FY 1991, we plan to continue implementing and expanding the activities we are initiating this year.

Question. The farm and safety initiative, as was discussed last year in these budget oversight hearings, was to be a sustained effort. What else needs to be done?

Answer. Certain agricultural safety and health activities, such as some program of surveillance to identify and respond to cases of disease and injury, and intervention to prevent cases from occurring, will have to be sustained into the foreseeable future, as long as work-related disease and injury continue to afflict rural populations. In FY 1991, we plan to continue implementing and expanding the activities we are initiating this year.

HEPATITIS B

Question. This Committee is concerned about the continuing increases each year in the number of hepatitis B cases. The incidence rate per 100,000 doubled between 1978 and 1981 and continued to increase resulting in about 300,000 new infections each year and about 4,000 deaths per year. In FY 1990 the Committee appropriated $10.5 million in new funding to address this problem. It has been said that if the AIDS epidemic had not appeared on the scene, hepatitis B would be the major health problem in this country. Yet, the fiscal year 1991 request for the hepatitis B program includes no increases. In your professional opinion, what more should be done to control this disease?

Answer: It is our professional opinion that control of hepatitis B in the United States can be accomplished through the prevention strategy outlined in the document provided to Congress upon request last year and entitled " Strategy for the Elimination of Hepatitis B in the United States". Several elements of this plan have now become a part of recommendations made by the Immunization Practices Advisory Committee (ACIP) of the US Public Health Service. One of these recommendations calls for the universal screening of pregnant women for hepatitis B infection, treatment of infants of infected women to prevent disease transmission from mother-to-infant, and immunization of susceptible household contacts of the identified mother. Another recommendation calls for the universal immunization of all infants born to immigrant or refugee Asian mothers as well as the universal immunization of all infants in populations with high rates of infection such as found in our Pacific Island jurisdictions. The final component of the elimination strategy calls for the universal immunization of either infants or adolescents to eventually control hepatitis B infection in this country.

It is our opinion that the implementation of universal screening of pregnant women and universal immunization of infants in selected populations with high rates of infection is feasible at this time. There is strong support for these recommendations and activities in the medical community; the major barrier to implementation being resources to offer these services to women and infants getting healthcare in the public sector. The funds appropriated for FY 1990 are being directed towards the implementation of universal screening of pregnant women, treatment of identified infants and immunization of other household contacts of the hepatitis B infected mother. The current level of funding will provide screening for 56% of the estimated 1.8 million pregnant women who receive their prenatal care in the public sector. Of the 18,000 HBV infected women estimated to be identified through universal screening, the majority (79%) are from minority groups. For blacks and Hispanics, prenatal screening for HBsAg will be complicated because of the high rates of women who have little or no prenatal care. Screening at the time of delivery and follow-up of infants born to these women will take extra efforts. We estimate that an an additional $4 million is required to fully fund the proposed programs for universal screening of pregnant women, treatment of their infants and immunization of their household contacts.

Many infants of immigrant and refugee Asian mothers who become infected with hepatitis B are not born to hepatitis B infected mothers . They acquire their infections from other family members or from other infected children and adults in their immediate community. Annually, an estimated 96,700 infants are born to Asian immigrants or refugees. It is estimated that 6,700 (7%) will become infected by five years of age and 1,700 (25%) will remain chronically infected. In the Pacific Islands under US jurisdiction (American Samoa, Federated States of Micronesia, Marshall Islands, Palau, Guam, and Saipan) approximately 10,000 infants are born annually and 85% obtain their immunizations in the public sector under the CDC Immunization Grant Program. The ACIP now recommends that all of these infants receive hepatitis B vaccine as part of their routine childhood immunizations. The estimated cost to the Department of the Interior of immunizing the children these populations is $2.7 million. The direct costs for operations and evaluation of these components of the program is about $1.5 million.

If the resources for the above activities are available over the next several years, a framework will be in place on which to build the next part of our comprehensive hepatitis B control program, namely the universal immunization of children. Several operational questions need to be answered before we launch into this effort and we will begin to address them with the direct funds appropriated to CDC. One question to be answered is which age group or groups to immunize and the feasibility of immunizing children. Based on the information and experience gained from our efforts in implementing the current hepatitis B prevention activities and from the pilot projects we should have proposals about universal childhood immunization for hepatitis B in the next 1-2 years.

These estimates and recommendations represent the professional opinion of CDC staff which have not been weighed against other competing priorities within either CDC or the rest of the Department.

Question. Even though we now have an extremely effective vaccine, there are a growing number of infants born with this disease, as the virus is passed on by their infected mothers. What is being done to locate pregnant women who are infected and to vaccinate their babies?

Answer. The Immunization Practices Advisory Committee of the US public Health Service recommended in 1988 that all pregnant women be screened for hepatitis B infection to protect through immunization infants born to infected mothers . A growing number of obstetricians are screening pregnant women and the American College of Obstetrics and Gynecology is preparing guidelines to cover hepatitis B screening in pregnancy. Several state and local health departments have begun programs to test pregnant women for the hepatitis B. Preliminary surveys from these projects indicate that they have been successful in testing pregnant women during their prenatal visits. However, women who do not receive prenatal care or who receive minimal prenatal care will pose a problem for testing, how best to assure screening and follow-up of infants is not known at this time.

The Congressional FY 1990 appropriation will initiate a program for universal screening to prevent mother-to-infant transmission of hepatitis B for women and infants receiving health-care in the public sector. Of the funds appropriated for FY 1990, approximately $8.0 million will supplement state and local level programs to prevent mother-to-infant hepatitis B infection, which is being done through the Immunization Grant Program. Guidelines are currently being sent to the states so that they can develop requests for program grants. A contract has already been negotiated for obtaining hepatitis B vaccine whichwill reduce the price of treating these infants from approximately $150 to $65. Mechanisms are being put into place to evaluate the success of programs but information will not be available until late 1991, except for those states that have currently initiated their own programs. The apparent success of the existing programs in identifying and vaccinating these high-risk infants suggests that there will be a high rate of acceptance of maternal screening.

MEASLES/IMMUNIZATION

Question. Investigations of recent outbreaks of measles indicate that age-appropriate immunization levels of our inner-city, socioeconomically disadvantaged children may be as low as 50 percent. In FY 1990, new funds were given by this committee to improve the measurement of actual immunization levels in defined populations, and to identify and demonstrate effective intervention activities that will improve age-appropriate immunization particularly in the inner-city areas of our country. What progress is being made in implementing these important activities?

Answer. The Program Announcement for Immunization Project Grants is being revised to focus attention on the immunization needs of the medically underserved and to require retrospective assessments of levels among preschool children. Standardized procedures for assessing immunization levels are being developed. For the first time since 1985, we will obtain a national estimate of vaccination coverage in the preschool population. Future assessment activities will include developing and evaluating methodologies to provide more accurate estimates of preschool immunization levels. Intervention activities to improve immunizations, particularly in inner-city areas, include developing effective techniques for increasing consumer demand, awarding contracts/cooperative agreements to develop educational/promotional materials, demonstrating the impact of "model" immunization programs, and evaluating new approaches to raising levels among preschool children and the cost-effectiveness of different methods of increasing parental interest/awareness.

TUBERCULOSIS

Question. There has been significant ongoing decreases in reported tuberculosis cases for decades. However, since 1985, this downward decline has leveled off and in some populations increases have been seen.

In April 1989, Dr. Louis Sullivan, the Secretary of Health and Human Services, announced a strategic plan for the elimination of tuberculosis in the United States. In FY 1990, additional monies ($1.8 million) were made available to begin implementation of this plan.

What is the current status regarding implementation of the plan? How were the additional monies used?

Answer. There has been a dramatic leveling off of previous yearly declines in the number of TB cases reported. It is estimated that more than 15,000 excess cases have accumulated from 1985 through 1988. This overall trend actually masks an increase in TB among young blacks and Hispanics while TB among non-Hispanic whites continues to decline. The excess cases occurring can largely be attributed to TB occurring in persons with HIV infection. HIV infection weakens the immune system and allows latent tuberculosis infection to progress to active disease.

Tuberculosis has retreated into focal geographic areas and demographically well-defined populations which can be targeted for intensified control and elimination efforts. The strategies and tactics have been devised and only need to be implemented.

The Strategic Plan for the Elimination of Tuberculosis in the United States has been formally endorsed by many public and private providers including, the American Medical Association, the American Lung Association, the American Public Health Association, and the American College of Preventive Medicine. In addition, at least 14 areas have established tuberculosis elimination advisory committees and 2 States and 3 cities have developed area-specific TB elimination plans.

The new monies for FY 1990 brought total CDC resources devoted to TB control to $21.6 million, of which $8.3 million are for TB cooperative agreements with the States, and $7.9 million are for TB/HIV control projects and $5.4 million are for technical assistance, biotechnical research, and technology transfer. These funds will allow CDC to begin implementation of all three steps of the elimination plan.

> Step 1: Proven cost-effective prevention and control methods will be more widely and vigorously applied. Resources will be targeted to address those most impacted by TB, e.g., racial and ethnic minorities, the homeless, and immigrants and refugees. The number of outreach workers available to provide directly-observed therapy and other services to TB patients will be increased.
>
> Step 2: Funds will also be made available for preliminary research on new diagnostic and treatment methods.
>
> Step 3: Technology transfer will be enhanced through the support of experienced program managers requested by States and cities, through limited support for laboratory training, encouragement of increased collaboration between providers and patient advocacy groups, and through development of new training and educational materials for targeted audiences.

As with the prevention and control monies, the majority of the new funds will be directed primarily to high-incidence areas, such as the Nation's inner cities.

Question. In your professional judgment, what will be the total cost to achieve elimination?

Answer. To achieve elimination, the Federal government will have to continue to provide national leadership and coordination. In CDC's professional judgement, this will require an increase in expenditures. The majority of increased funds to CDC would be given through cooperative agreements to State and local governments to increase and expand their activities. Most of the funds are directed primarily to high-incidence areas, such as the Nation's inner cities and to high-risk populations, such as the foreign-born. The funds are used for operational support and to hire outreach workers to administer directly-observed therapy to otherwise non-compliant patients. Cure of TB requires 6 to 9 months of continuous therapy. Persons who do not faithfully take their medications continue to spread infection in the community. At least 20 percent of TB patients require directly-observed therapy to cure their disease and prevent spread of infection and disease to the larger community. Current levels of funding allow the hiring of enough outreach workers to provide directly-observed therapy to about 10 to 12 percent of these patients.

The Food and Drug Administration (FDA) would need additional monies for research and regulatory oversight for new diagnostic and treatment modalities. The National Institutes of Health, National

Institute of Allergy and Infectious Diseases (NIH, NIAID) will need increased funding to expand basic TB research activities. These activities include the application of recombinant DNA technology to develop a TB vaccine and new diagnostic tests, immunological studies of host factors which influence susceptibility and resistance to disease, and application of modern technology to develop new preventive and curative treatments. Both of these agencies work in close collaboration with CDC.

The following table shows the budgets for CDC, FDA, and NIH/NIAID that would be needed to fully implement the plan. All monetary figures represent 1990 dollars.

TUBERCULOSIS—COSTS

Year(s)	CDC $ (Yr*)	FDA $ (Yr*)	NIAID $ (Yr*)	Total Expenditures
1990	36.0	3.5	16.0	55.5
1991-1994	144.0(36.0)	5.6(1.4)	64.0(16.0)	213.6
1995-1997	18.9(6.3)	0	24.0(8.0)	42.9
1998-2000	9.3(3.1)	0	1.5(0.5)	10.8
2001-2010	15.0(1.5)	0	0	15.0
Totals (Million)	$223.2	$9.1	$105.5	$337.8

*Annual Budget

POLIO

Question. Even though virtually eliminated in the United States, polio is still a major public health problem worldwide with over 250,000 cases estimated each year. The World Health Organization has established the goal of global eradication of polio by the year 2000. What activities should the United States support in this effort. How much money would we save in the United States if polio is eradicated from the world?

Answer. The United States could provide technical assistance and laboratory support that could be used to improve the public health infrastructure in the developing world, improve their technique for surveillance and outbreak control investigations, increase their laboratory capacity and technology, and train a group of epidemiologists, laboratory workers, and support personnel in each country who can be used to administer and evaluate other

important public health programs for years to come. Each year approximately 20 million of doses of polio vaccine are administered in the United States. If polio were eliminated from the world, savings of approximately $300 million annually in vaccine and vaccine administration alone would be realized in the United States.

NOTE: The $300 million is calculated as follows:

Approximately 20 million doses of OPV are administered per year in the U.S.

Half (10 million) doses in the public sector @ $2.00/dose plus $3.00 per dose for administration - $5.00 x 10,000,000 or $50,000,000.

Half (10 million) doses in the private sector @ $10.00 /dose plus $15.00 per dose for adminitration - $25.00 x 10,000,000 or $250,000,000.

Total - $50,000,000 + $250,000,000 or $300,000,000.

STOCKPILE

Question. The vaccine stockpile is designed to ensure that there is no interruption in vaccine production. You have not requested funds in 1991 for the vaccine stockpile. What is the current status of the stockpile?

Answer. Steady progress has been made toward establishing a 6-month stockpile of routinely used vaccines. By the end of 1990, 90 percent of each antigen in the original stockpile is expected to have been purchased.

BREAST AND CERVICAL CANCER

Question. Last year the Committee included $5 million to begin a new initiative to reduce the incidence of breast and cervical cancer. It is estimated that in this year alone, an estimated 142,000 new cases of breast cancer will occur, and an estimated 43,000 women will die from the disease. Cervical cancer results in approximately 6,000 deaths annually. The technology and knowledge exist to substantially reduce these unnecessary deaths.

What is CDC currently doing to implement the program started by the Committee last year?

Answer. The FY 1990 Senate Appropriations Report language directed CDC to "provide a focus at the national level and initiate State-based programs that, when fully funded, will prevent needless deaths from breast and cervical cancer in women."

In keeping with that language, CDC will direct approximately one-third of the $5 million total to directly support State breast and cervical cancer prevention programs. Assistance will be provided to 3 to 4 States in the initiation of comprehensive screening programs for the early detection and follow-up of breast and cervical cancer. Support will be provided to an additional

State to augment existing screening and follow-up activities, resulting in a comprehensive breast and cervical cancer program in that State. State support will include the assignment of CDC field staff to assist in program design and implementation.

The remaining two-thirds of the $5 million will be directed toward the establishment of key core elements to serve as a base for a strong national program to prevent breast and cervical cancer. These elements are: information/education campaigns to educate women on the value of regular screening for breast and cervical cancer; education campaigns for health care professionals (including allied health professionals) to promote high-quality screening and effective follow-up; the development of standards, training, and tracking systems to ensure screening tests are of the highest possible quality, and; the augmentation of breast and cervical cancer surveillance systems to better target prevention resources and evaluate program effectiveness.

Together, these core elements will establish the basis of a framework for breast and cervical cancer prevention from which all States will benefit.

Question. I understand that early detection and treatment for breast and cervical cancer would substantially reduce the number of deaths from these diseases.

What would it take for us to realize meaningful reductions in breast and cervical cancer and what would it cost?

Answer. A substantial number of these breast and cervical cancer deaths could be prevented through early detection and appropriate follow-up.

- It is estimated that mortality from breast cancer could be reduced by more than 30 percent if women were screened according to current guidelines. Survival from breast cancer is significantly improved if it is detected early. Yet only one-half of all women with malignant breast cancer in this country are diagnosed when their disease is still at an early stage. This is true despite the proven value of mammography and physical examination in the early detection of this disease.

- Although mortality from cervical cancer has decreased 70% during the last 35 years, the fact that an estimated 6,000 women will die this year from this disease is tragic given the effectiveness of early detection and treatment for cervical cancer. While the Pap smear tests have been used for more than 40 years, 27% of women in this country have not had a Pap smear test in the previous 3 years. Essentially all deaths from cervical cancer are preventable. However, underutilization of screening and lack of prompt diagnostic follow-up and treatment continue to result in unnecessary death in this country from this disease. Recognizing this, the Congress included provisions in the 1989 Omnibus Budget Reconciliation Act (OBRA '89) that allows Medicare to cover the cost of cervical cancer pap smears for female beneficiaries.

- Effective programs for prevention of mortality from breast and cervical cancers need five components: Availability of screening; follow-up and prompt treatment of those found to have disease; public and provider education; quality assurance of the screening procedures; and timely monitoring of the effectiveness of these activities.

  CDC estimates that it would cost about $5-7 million per State, or about $250 - 300 million per year on a national basis, to pay for screening services for women currently uninsured and support the above components. This estimate does not account for the expansion of Medicare coverage for pap smears in OBRA '89, and does not include treatment costs, since they will be incurred regardless of whether screening is available--the number of women who are not screened will eventually be diagnosed, although with more advanced disease.

Question. We know that many of the deaths from breast and cervical cancer are avoidable with the proper use of known technology.

Why aren't we applying that technology?

Answer. Most of the estimated 6,000 deaths caused by cervical cancer each year could be prevented through early detection and appropriate follow-up. While the Pap smear screening test has been available for more than 40 years, 27% of women have not had a Pap test in the previous 3 years. Women who are older and low-income are at higher risk for cervical cancer and are least likely to be screened. Many health care providers do not take advantage of a woman's visit to review her Pap smear history and to take a Pap test. Once women are screened, we must ensure the quality of the screening test and timely follow-up for women with abnormal tests.

Reducing deaths from cervical cancer requires a step-by-step system leading to early detection and appropriate follow-up. The system, though ostensibly straightforward and well-defined, has many potential points for breakdown. The patient, health care provider, and laboratory play key roles, which must be played well, to ensure that each step is performed optimally and without delay. The cost of services, particularly of mammography and follow-up care for identified cancers, is a clear barrier to the uninsured population's seeking services.

LEAD POISONING PREVENTION

Question. In fiscal year 1990, the Committee provided $4 million to develop a national childhood lead poisoning prevention grant program. Lead poisoning in children is a major public health problem in the U.S. It is estimated that 3 to 4 million children have high enough blood lead levels to cause adverse health effects and that the problem is particularly serious and widespread among the minority poor and inner city children, many of whom live in older, deteriorated and dilapidated housing where lead is found in paint, dust, and soil in high concentrations.

How does the magnitude of the childhood lead poisoning problem compare to other childhood diseases?

Answer. Childhood lead poisoning remains the most common environmental disease in children. In 1986, around 12,000 lead poisoned children were identified by ongoing screening programs. This is many more than the number of children reported to CDC with any infectious diseases for which reporting systems exist, including asceptic meningitis, mumps, whooping cough, and meningococcal infections. Thus, childhood lead poisoning is a serious concern, as are other childhood infectious diseases.

Question. What are the impediments to eliminating the problem of childhood lead poisoning within the next decade?

Answer. We will not eliminate childhood lead poisoning by merely screening and medically treating children with this disease. The only way to eliminate childhood lead poisoning is to prevent it from occurring, which means ensuring children have no access to environmental sources of lead. The greatest impediment to eliminating this disease is the high cost of abating lead-contaminated paint and paint-contaminated dust and soil from older housing.

IMMUNIZATION/MEASLES

Question. In 1989, there were provisionally more cases of measles (16,236) and measles-related deaths (43) reported in the United States since 1978. Will the American Academy of Pediatrics (AAP) and the Advisory Committee on Immunization Practices (ACIP) recommendations for a 2-dose MMR schedule reduce the number of measles cases?

Answer. The AAP recommendation calls for the first dose to be administered at 15 months of age and the second dose upon entry into junior high or middle school. The ACIP recommendations call for the first dose to be administered at 15 months of age and the second dose upon first entry into school. Both also recommend a second dose upon entry into college if two doses have not already been administered. When fully implemented, these recommendations should essentially eliminate the measles cases which are now occuring in junior high school, high school, and college. Over 8,000 cases were reported in school-aged-children in 1989.

Question. In your professional judgement, what will it cost to implement these new recommendations in the public sector?

Answer. Each year approximately 4.0 million children enter school for the first time and approximately 2.4 million young adults enter college for the first time. If we assume that about 50 percent of these students will continue to be served by the private sector (3.2 million), the remaining 3.2 million children would have to be served by the public sector. At the current Federal cost of MMR vaccine ($14.74/dose), $47.1 million a year would be required to implement the 2-dose MMR schedule in the public sector through Federal, State, and local resources.

Question. What is CDC doing about the number of health workers that are at risk of hepatitis B infection?

Answer. CDC's efforts to prevent occupationally acquired infections have been primarily in two areas, getting information about risk and making recommendations. We have identified and quantitated the risk of occupational hepatitis B infection through special epidemiologic studies and national surveillance for hepatitis B which identifies risk factors for infection.

In 1981, CDC developed recommendations adopted by the Advisory Committee on Immunization Practices that healthcare workers with frequent exposure to blood receive hepatitis B vaccine. In 1985, these recommendations were broadened to include immunization of students in the healthcare fields during their professional training. In 1987, prevention of occupationally acquired hepatitis B through immunization and the use of appropriate barrier techniques was re-emphasied in what has been termed "universal precautions" for the prevention of HIV infection in the health-care setting.

CDC has served as a technical consultant to the Occupational Safety and Health Administration (OSHA) in the development of the proposed rule to prevent occupational exposure to bloodborne pathogens in the workplace. In addition, in response to PL 100-607 (The Health Omnibus Programs Extension Act of 1988), CDC developed guidelines for the prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public safety workers. All of these guidelines have recommended the use of hepatitis B vaccination as the primary means of preventing hepatitis B infection.

Question. Has CDC developed any guidelines for use by health-care workers on the dangers of exposure to hepatitis B?

Answer. All of the recommendations and guidelines previously described and dating back to the mid-1970's have described the occupational risk of hepatitis B infection to health-care workers.

Question. Should immunization for hepatitis B be mandatory for healthcare workers?

Answer: CDC feels that vaccination should remain voluntary for all eligible employees. A strong program of education on the occupational risks and consequences of hepatitis B, and the safety and effectiveness of hepatitis B vaccine, must accompany any vaccination effort. In addition, strong endorsement of vaccination by the leading medical authorites at the worksite has been shown to significantly improve vaccination acceptance.

Vaccination and education of students during professional training for the health-care fields is one of the most effective ways to prevent hepatitis B infections. This prevention appoach is now widely implemented in medical and dental schools but has not been significantly instituted in the other health professions.

EPIDEMIOLOGY

Question. CDC has a very successful history of sending out young scientists to investigate serious public health problems all over the country and the world. The disease detectives have been instrumental in protecting the country from polio, Legionnaire's disease, toxic shock syndrome, and on and on. It is the committee's understanding that we, as a nation, are in short supply of these well-trained epidemiologists needed to reduce unnecessary public health problems of today and tomorrow.

What is CDC doing to address this need?

Answer. CDC's major effort to meet this need is the Epidemic Intelligence Service (EIS) Program. The EIS is a 2-year program in-service and on-the-job training in applied epidemiology. It was created in 1951 and has graduated over 1,600 public health professionals trained in epidemiology to address the important public health issues of the day. The EIS helps CDC to: carry out its mission to prevent and control disease; increase the number of field-trained epidemiologists in the U.S.; and to provide epidemiologic assistance to State and local health departments and improve disease and injury surveillance nationally.

CHRONIC DISEASE RISK FACTORS/CONTROL & PREVENTION

Question. It would seem that many of the risk factors for chronic diseases such as heart disease, cancer, stroke, diabetes are similar--for example smoking, lack of physical activity, diet, lack of medical services.

Is our tendency to focus on individual diseases inefficient? And could we develop a better coordinated program that would control and prevent these problems in a more cost-effective way?

Answer. To best prevent and control the chronic diseases, we need a combination of integrated chronic disease interventions and targeted disease-specific activities. Thus, we undertake targeted control programs for cancer, diabetes, and heart disease. However, these diseases usually share common risk factors, and it is both more efficient and cost-effective to promote a healthy lifestyle and address these risks regardless of disease labels. Thus, we also support State programs to deliver comprehensive preventive services in their health care delivery component--when a woman comes in for a blood pressure check, she should be evaluated for needing cervical and breast cancer screening. Smoking cessation counseling should be part of all health care visits, and smoking prevention efforts should be underway in every community. We work with the States to develop a coordinated program focusing on risk factors such as smoking, diet, and physical inactivity--relevant to many chronic diseases.

CONSTRUCTION INDUSTRY

Question. The Construction Industry Institute estimates that every $100 of construction costs $1.75 in worker compensation premiums, resulting in an estimated cost of $6 billion a year in workers compensation. The construction industry has the second greatest number of traumatic occupational fatalities of any industry, approximately 15% of all industries combined.

The FY 1990 appropriation provided $1 million to increase efforts addressing this hazardous industry.

What activities and plans is NIOSH pursuing?

Answer. One-half of the funding increase for construction safety and health will be dedicated to an extramural program that will fund investigator-initiated projects for construction site injury and illness prevention efforts to protect construction workers from worksite hazards. These extramural grants will target potential labor-management demonstration projects.

One fourth of the funding is targeted for a State model construction safety and health program. This effort is intended to address the problem that most construction employers are small businesses that frequently do not invest in safety and health consultation as do many large industrial enterprises. In this program, the State government will send safety and health consultants to the construction sites to assist these businesses in preventing work-related injuries and disease.

The remaining fourth of funding will be used to broaden existing NIOSH programs in construction safety and health. These efforts include projects for making available safety and health information and training, conducting research on asbestos substitutes used in the insulation industry, conducting surveillance of construction hazards, and developing/evaluating "control" technology needed to prevent exposure of workers to hazardous substances and mechanical forces.

Question. Are the FTE's associated with that increase in funding on board?

Answer. We expect to have recruited persons for these 10 FTE's by May 1990.

MUSCULOSKELETAL DISORDERS

Question. Ergonomic problems, including carpal tunnel syndrome, are rapidly increasing. What research and other activities is NIOSH conducting and planning to address this growing health issue?

Answer. NIOSH is conducting a broad range of research to address work-related musculoskeletal disorders affecting the upper and lower extremities, typically due to repeated trauma, as well as low back problems arising from overexertion in lifting tasks. This ergonomic research includes studies to develop improved methods for characterizing the disorders, defining risk factors in their etiology, interventions to reduce their occurrence, expanded surveillance to target occupations presenting the greatest risks, and improved means for recognizing job hazards posing musculoskeletal problems. NIOSH's research findings are disseminated in the form of manuals, work practices guides, and special technical reports that provide occupational safety and health practitioners with innovative control strategies and recommendations for preventing musculoskeletal disorders.

The following projects - recently completed and ongoing, exemplify the activities in this program:

Methods Development

1. Preventing Cumulative Trauma Disorders (CTDs) of the Lower Extremity This study was the first comprehensive effort to investigate the causes of knee and leg injuries among workers most at risk to these injuries, notably miners who kneel while working and workers who install floors and carpets. Through this research, NIOSH has invented methods and technology for measuring the extent and duration of repeated trauma to the knee and the resultant damage to the soft tissue within the worker's knee. This progress is essential to further research for preventing injuries resulting from repetitive knee trauma.

2. NIOSH Atlas of Low Back Tests/Measures This project is presently attempting to validate a NIOSH-developed method that can be used by health care practitioners when assessing low back musculoskeletal injuries, necessary to further research for the prevention of low back injuries.

3. Shoulder/Neck Muscle Tension for Repetitive Work This research will (1) determine job factors (repetition rate, work height, and research distance) that accelerate the onset of soft tissue pain and fatigue during overhead lifting tasks, and (2) provide ergonomic guidelines for designing jobs to reduce chronic muscle fatigue associated with these tasks.

4. Health Care Industry--Low Back Epidemiologic Studies The objectives of this project are to (1) identify health care workers who are vulnerable to back injury; (2) assess factors which may contribute to this risk; and, (3) identify feasible and effective methods for reducing this risk. Nursing assistants working in geriatric care facilities were shown to have the highest rate of back injuries among those employed in the health care industry. Current work will evaluate the use of patient handling equipment such as, shower chairs, hoists, and ambulatory belts to avoid patient lifting. A trial study is underway in a nursing home to determine the staff acceptability of using this equipment to meet patient handling needs.

5. Ergonomic Risks from Tool Usage and Design This project is designed to evaluate the efficiency of certain tool-related interventions for reducing the grip force requirements of manual tasks. The results of this study may support recommendations for tool design modifications and control strategies to reduce risk factors contributing to the development of cumulative trauma disorders.

6. NOES/NOESM Outputs in Ergonomic Rates of Musculoskeletal Injuries This surveillance project is using data from two major NIOSH surveillance efforts (the National Occupational Exposure Survey and National Occupational Health Survey of Mining) to derive nationwide probabilities for worker exposure to 18 ergonomic and physical agent hazards identified in the industries surveyed, and nationwide probabilities for worker exposure to 12 ergonomic hazards identified for the different types of mining operations surveyed. The six most probable hazards identified in general industry were (1) passive postures; (2) shoulder transports; (3) arm transports; (4)

lifting postures; (5) hand/wrist manipulations; and, (6) finger manipulations. The industries that appeared to expose workers to the greatest number of hazards include: (1) special trade contracting; (2) food and kindred products; and, (3) textile mill products. Four ergonomic hazards provided the greatest potential threat to mine workers. These four hazards were (1) arm and shoulder movements; (2) finger/hand movements; (3) heavy lifting; and, (4) neck/back movements. The probability of being exposed to one of these four hazards equaled or exceeded 50% of the workers for at least one of the types of mines surveyed. The types of mines that appeared to expose workers to ergonomic hazards most frequently were (1) aluminum ore; (2) potash; (3) sodium compounds; and, (4) nonmetallic minerals. Draft reports of the findings of this project are being finalized for publication.

7. National Estimate of Work-Related Cumulative Trauma Disorders (CTDs). Using the most important NIOSH and other federal data bases, NIOSH will develop a national estimate of the incidence, and medical and social costs, of CTDs for the upper/lower extremities and the back.

INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

Question. In FY 1990, NIOSH received $250,000 for continuing support of the Institute of Occupational Health and Safety at West Virginia University. Please describe what progress is being made in developing their occupational safety and health training and research program.

Answer. The Institute is approaching the second half of its second year of NIOSH funding, and has already made considerable progress which include:

- Established masters of science programs in occupational safety and health for engineering students, and in occupational toxicology for medical students.
- Arranged field experience in occupational medicine with local industry, State agencies, NIOSH, and coordinated training for occupational medicine students across medicine departments (dermatology, pulmonary, etc.).
- Established collaborative training and research between the business and engineering colleges and departments of pharmacology and toxicology for training engineers and business students in occupational safety and health, and for conducting multidisciplinary research.
- Providing general occupational medicine education to all medical students, and electives in occupational medicine for fourth-year students.
- Providing training in clinical medicine for the management of selected occupation disorders, such as low back pain.

- Established a telephone service providing occupational safety and health education and consultation to the public, and especially to health practitioners. Also established a Statewide program of continuing education to inform health practitioners, business leaders, and managers and owners of small businesses on common occupational safety and health problems in the State.

- Initiating a program of medical research training, that will first establish research problems of highest priority for addressing the needs of the State.

AIDS PROJECTIONS

Question. There was a recent announcement that AIDS projections have been lowered. Please explain the recent revisions of the number of persons in the U. S. infected with HIV. What are the public health implications of these data in terms of projections of AIDS cases CDC is making for 1990-93?

Answer. Estimate of HIV Infection--CDC now estimates that approximately 1 million persons in the United States are infected with HIV. This calculation is based on survey data that have become available in 1989 and on analyses using statistical methodologies developed during the last few years, and others over the last several months. These methods yield individual estimates of about 650,000 to 1,400,000 infected persons. The wide range reflects inherent uncertainties in the past surveys and differing assumptions underlying various statistical procedures. The current estimate is at the lower end of the range of 1 to 1.5 million persons infected provided in 1986. That estimate was based on very limited data, and few HIV surveys (the antibody test was licensed in 1985). We now estimate that about 750,000 people were infected with HIV by early 1986. Based on survey data from active military personnel and childbearing women, we believe there were at least 40,000 new HIV infections in the United States during 1989. The spread of HIV in this country continues.

Projections for AIDS Cases--Late in 1989, CDC convened a meeting of experts -- more than half from outside the Public Health Service -- to estimate the number of AIDS cases that would be diagnosed in the United States from 1989 through 1993. They predicted that the number of cases diagnosed would increase in each successive year. The middle of the range of projections for each year is about 15 percent less than the corresponding prediction made by the Public Health Service in June 1988.

Through 1988, we estimate that 120,000 AIDS cases were diagnosed in the United States and that a diagnosis will be made on 45,000 cases during 1989. We project that 390,000 to 480,000 cumulative AIDS cases will have been diagnosed by the end of 1993.

PEDIATRIC AIDS

Question. Most recent statistics report the number of pediatric AIDS cases at approximately 2,000 and it is our understanding that these cases are climbing. What is CDC investigating regarding pediatric AIDS? What is CDC doing to prevent pediatric AIDS?

Answer. CDC is conducting serosurveys of newborns in 44 States, the District of Columbia and Puerto Rico to estimate the number of infants newly infected with HIV. The results are used to estimate the numbers of children likely to develop HIV-related illness, including AIDS, over the next few years. This information assists in directing public health prevention programs and in developing health care services for those in need. The serosurveys are an ongoing project, carried out in collaboration with State health departments and the National Institute of Child Health and Human Development (NICHD). CDC also continues to support national surveillance activities for adult and pediatric AIDS through financial and technical support to State and local health departments. A number of States have made HIV infection reportable, and CDC has collaborated with them in developing a standard set of minimal data for HIV reporting. In 1988, CDC began a collaborative project for expanded surveillance of HIV in children in 6 different geographic locations (States or metropolitan areas). Data from this project will provide more information on the full spectrum of HIV disease in children, and document the health care and social service needs of this special population. Estimates on HIV incidence derived from newborn serosurveys indicate 1,500 to 2,000 infants (0.5 per 1000 births) will acquire HIV infection from 4500 to 6000 infected pregnant women in 1989.

CDC is supporting studies of HIV-infected women and their children to better determine the frequency, timing, and risk factors for transmission from mother to infant; the effect of HIV infection on pregnancy; and the disease progression in infants. These studies will lead to more focussed prevention and treatment efforts. One of the greatest needs in pediatric AIDS is improving the ability to diagnose the infection in infancy. Since one third of children born to infected women will be infected themselves, it is very important to establish the diagnosis as soon as possible to provide infants with the benefits of early medical intervention. CDC is investigating a variety of methods to help diagnose infection in infants, through development of new laboratory tests and field evaluation of them. Included are: tests based on the polymerase chain reaction (PCR), which directly detects the virus in cells; new serologic tests, such as assays of IgA and IgM antibody, which are manufactured by the baby in response to infection; and in vitro antibody production techniques, where cells from the baby are stimulated in the laboratory to produce antibodies to HIV. These techniques, and others developed by collaborators, are being evaluated in CDC-supported follow-up studies of infants born to infected mothers.

CDC supports a number of HIV prevention activities in this area. First, perinatal HIV prevention projects are funded in eight areas to: determine and seek to overcome obstacles to effective use of contraception among target populations; facilitate the use of family planning services among the target population; evaluate attitudinal factors related to use of contraception among HIV-infected and high-risk women; and encourage behavioral change among HIV-infected and high-risk women to reduce risk of acquisition or transmission of HIV. CDC has also worked closely with the Office of Population

Affairs to include HIV prevention training in programs carried out by Title X Family Planning regional centers.

HEALTH CARE WORKERS

Question. We are aware of the question of risks of HIV transmission to health care workers. What methods are being brought to bear by CDC to protect health care workers?

Answers. CDC conducts ongoing surveillance, research, and prevention activities related to the occupational risk of HIV infection in health-care workers (HCWs). Surveillance of HCWs with AIDS is conducted in collaboration with State health departments and is currently being expanded to include workers with occupationally-acquired HIV infection who do not meet the AIDS case definition. In cooperation with over 300 hospitals, surveillance of health-care workers, following occupational exposure to blood of patients with AIDS or HIV infection, has been conducted since 1983. This system has been useful in estimating the risk of HIV infection in workers after a documented exposure to blood of patients with AIDS or HIV infection and in evaluating the use of zidovudine as post-exposure prophylaxis. Through examination of workman's compensation claims, surveillance in selected States is being extended to include all workers who provide patient care.

Ongoing research includes monitoring HIV seroprevalence of patients in selected hospitals and clinics, determining the risk of HIV infection after various types of contact with HIV-infected blood, and documenting the frequency and circumstances of contact with blood and certain body fluids among HCWs in hospital emergency departments, operating and delivery rooms, prehospital care providers (paramedics/EMTs), and morticians. These studies assess the knowledge and attitudes of HCWs, the extent of compliance with precautions recommended by CDC and others, and the efficacy of these precautions in preventing contact with blood and body fluids. CDC has assisted in conducting an HIV seroprevalence survey in a large group of dentists and has also proposed similar studies in other clusters of HCWs with frequent blood contact, e.g., surgeons. Laboratory studies have been carried out to devise disinfection and sterilization techniques. Studies have evaluated the potential for aerosolization of blood and bloodborne pathogens during procedures in dental operatories, hemodialysis units, and are in progress to evaluate these questions in hospital facilities, as well.

After consultation with outside experts, CDC has developed guidelines to prevent occupational transmission of HIV and other bloodborne pathogens. The first departmental guidelines were published in November, 1982, one year before the AIDS virus was discovered. Recommendations are continually revised as new scientific data become available. A curriculum has been devised for public safety personnel, and videotapes and other educational materials have been provided for dental and hemodialysis staffs. CDC guidelines for prevention of transmission of HIV and other bloodborne pathogens in health-care settings have served as a foundation for a wide variety of national and international organizations to develop appropriate recommendations. CDC has also consulted with many professional associations in developing its guidelines.

HIV COUNSELING AND TESTING

Question. CDC awards more than $100 million per year for both anonymous and confidential HIV counseling and testing services at more than 4,000 sites nationwide. Why does CDC place such emphasis on this intervention program and what do we get in return?

Answer. HIV counseling and testing programs are part of larger, more comprehensive HIV prevention programs that include:

- Referral and partner notification;
- Surveillance and seroprevalence studies;
- School-based primary prevention programs;
- Sexually transmitted disease programs;
- Drug treatment programs;
- Community-based education programs;
- Minority education activities;
- Special education prevention efforts directed to persons engaging in high-risk behavior such as persons using drugs, men who have sex with men, homeless, runaway youth, and persons in correctional justice systems.

Counseling, testing, referral, and partner notification programs are based on the premise that knowledge of HIV infection status and appropriate counseling can influence behavior changes that will reduce the risk of becoming infected or infecting others. Also, early detection of HIV infection can lead to appropriate immune system monitoring and medical management which can lengthen the period a person with HIV infection remains well.

HIV prevention and surveillance cooperative agreements with State and local health departments require that counseling and testing services be routinely offered at free-standing HIV counseling and testing sites and that these services be provided at existing facilities such as STD clinics, drug treatment centers, family planning and prenatal clinics, TB clinics, etc. This ensures easier access to those services for persons and populations at highest risk, such as men who have sex with men, intravenous drug users (IVDUs) and their spouses/sex partners, blacks, and Hispanics who engage in high-risk behavior.

Since 1988, the number of public health HIV counseling and testing sites has increased from 1,577 to 4,449. Allowing for persons who return anonymously for repeat testing, CDC estimates that approximately 2 million persons have been tested since 1985 and between 123,000 to 145,000 persons have learned of their HIV infection status through publicly funded counseling and testing sites. CDC estimates that approximately 1 million persons in the U.S. are infected with HIV. The 1991 budget requests $130 million in total for HIV counseling and testing activities.

INTRAVENOUS DRUG USERS

Question. We know that a high proportion of drug users are not in treatment programs and approximately 40 percent of injecting drug users have never been in treatment programs. How do street outreach programs assist in getting these persons into treatment and/or in changing their drug-use behavior?

Answer. Prevention of intravenous drug use (IVDU)-associated transmission of HIV depends on intravenous drug users entering treatment programs and stopping the use of drugs. In many communities, the number of IVDUs seeking treatment exceeds the capacity of treatment centers. Additionally, many IVDUs have relapsed or are not yet able to make the commitment to be drug-free. Street outreach programs represent the most important intervention available in many communities to reach out-of-treatment drug users. These programs employ former IVDUs from the community who work locally to deliver several educational messages.

Outreach programs refer IVDUs to drug treatment centers as well as HIV counseling and testing sites. Many programs have follow-up procedures for persons referred to assist them in getting to treatment facilities.

Question. How effective are they in changing behavior of drug users?

Answer. Data regarding the number of people reached (process evaluation) and the changes in risky behavior of IVDUs reached on the street (outcome evaluation) are currently being collected. Preliminary data suggest that many IVDUs reached by street outreach workers will seek treatment if it is available and the proportion cleaning their injection paraphernalia has increased substantially, at least partly as a result of education received from HIV prevention programs.

PARTNER NOTIFICATION

Question. We have heard that from 10 to 35% of spouses/sex partners of persons who have HIV infection are infected themselves. What is the role of the partner notification programs in this area?

Answers. Partner notification has been a component of sexually transmitted disease (STD) control programs for many years. Its purpose is to help individuals receive curative or preventive STD treatment. In recent years, partner notification has been increasingly applied in HIV prevention programs to assist in bringing focused prevention information to people at high risk of becoming infected by virtue of being sex and/or needle-sharing partners of individuals infected with HIV. Once located, risk reduction education can be targeted to these partners to help them and their partners engage in safe behaviors which will prevent further HIV transmission.

Partner notification begins by educating the person with HIV infection about the need to notify partners. Once trust has been established, decisions are jointly made regarding the procedure to be followed to notify partners at risk--using either patient referral or provider referral. The client may choose to notify his/her spouse or sex and/or needle-sharing partner (patient referral) and bring the person in for joint counseling or refer the partner to an anonymous or confidential testing facility. Alternatively, the person with HIV infection may elect to voluntarily give names of partners to local health officials and request that partners be confidentially notified (provider referral). Once partners of persons who are infected are notified of their exposure to HIV, they are then offered counseling, testing, and follow-up to determine their infection status. If these partners avail themselves of the voluntary testing program, counseling is then tailored to their infection status.

HIV COUNSELING AND TESTING

Question. We understand that publicly funded HIV counseling and testing programs currently provide services to nearly 1.5 million people per year and approximately 50,000 persons are found to be infected. Counseling and testing programs are designed to detect HIV infection early so that aggressive medical management can follow and to initiate behavior change leading to a reduction in HIV transmission. What do CDC and State health departments do to ensure that such persons are referred to competent physicians for follow-up care and that safe behavior is likely to follow?

Answer. HIV counseling and testing programs attempt to: promote behavior change that will reduce the risk of HIV infection for persons who are not infected; facilitate early detection of HIV infection in persons and to refer them to medical providers capable of providing follow-up care and medical management of HIV-related illnesses; prevent the spread of HIV infection by providing information to infected persons regarding behaviors essential to avoid transmitting of the virus to others; provide information about benefits of medical evaluation and treatment for individuals with low CD4+ cell counts; counsel persons who are infected to inform their spouses/partners especially those who are in continuing relationships and are, as a result, at high risk of becoming infected and; provide information, testing, and counseling to sex and needle-sharing partners of persons who are infected.

NATIONAL HOUSEHOLD SEROPREVALENCE SURVEY

Question. What is the status of the proposed national household seroprevalence survey?

Answer. The field work on the feasibility study for a household HIV Survey was concluded with the Dallas study on December 20, 1989. Overall response rates for both Dallas and Allegheny Counties exceeded 80%. Although this level of response is normally more than sufficient to produce unbiased population estimates, in the case of HIV (where the prevalence is estimated to be less than 1%), practically any nonresponse is a potential source of significant bias. The Dallas study included a number of procedures to assist in evaluating the nature and extent of nonresponse bias and analysis of that information is now under way.

Question. What have you learned from the field tests in Allegheny County and in Dallas County and is a national survey still being considered?

Answer. A final report on the feasibility study will be completed by May 1990. It will be thoroughly reviewed and a recommendation will be made to the Assistant Secretary for Health.

SEXUALLY TRANSMITTED DISEASES

Question. Has CDC's current emphasis on reducing syphilis in major metropolitan areas affected the progress made toward the prevention and control of gonorrhea during the 1980's?

Answer. Any decision which emphasizes one particular infection effects the amount of resources which can be dedicated to the others. These tradeoffs are a necessary part of STD policymaking. In 1989 and 1990, CDC has directed an increasing proportion of its STD control resources to major metropolitan areas with rising rates of syphilis to better reach "core" populations (low-income, heterosexual minority populations) and hard-to-reach foci of disease among "crack" cocaine users who are exchanging sex for drugs. This in turn has affected the amount of STD control activities which can be directed to gonorrhea. Unfortunately, in 1989, reported gonorrhea morbidity increased for the first time in 4 years. Twenty-two States had a higher gonorrhea rate in 1989 compared to 1988; in 10 of these States, this increase was greater than 10%. In addition, gonorrhea rates among blacks and teenagers remained at high levels, and the number and percentage of gonococcal strains resistant to standard therapies, primarily penicillin, increased substantially.

CHLAMYDIAL INFECTIONS

Question. National policy guidelines for prevention and control of chlamydial infections, which cause about 4 million acute infections annually, were developed in 1985. What has CDC done since that time to prevent and control chlamydial infections?

Answer. Since 1985, Federal, State and local STD officials have made substantial advances in developing prevention and control programs for chlamydia, while also addressing other competing STD priorities. Currently, 42 States have at least one city or county STD program that offers comprehensive surveillance, diagnostic, testing, and treatment services. Three States enacted laws requiring the reporting of chlamydia during 1989, bringing the total with such laws to 33 States. In 1989, over 60,000 patients with chlamydial infection were interviewed regarding their sex partners, and nearly 50,000 sex partners were referred for examination. Over 1.4 million women were screened for chlamydia, with 14% found to be positive. As a result of these activities, over 80,000 potential cases of genital chlamydial infection were prevented. These 1989 activities reflect a threefold increase over those delivered in 1988.

UNSAFE SEXUAL BEHAVIOR

Question. Is there any evidence that current efforts to reduce unsafe sexual behavior has worked in this country? If so, in what populations? If not, why not?

Answer. To date, the only group which has markedly reduced its unsafe sexual behaviors has been white men who have sex with other men. During the 1980s, sharply decreasing rates of syphilis, gonorrhea, hepatitis B, and enteric infections in this group attested to the behavioral impact of HIV prevention messages. However, in other groups, STD trends imply that safer sexual behaviors have not yet been adopted. Syphilis rates have been increasing in low-income, urban and rural, minority heterosexual populations. The rate of gonorrhea has increased in teenagers while decreasing in older age groups. Clearly, public health officials need to better target their STD/HIV prevention messages to those populations at highest risk in an effort to reduce unsafe behaviors. Ultimately, this would have spin-off benefits of lowering all sexually transmitted infections.

CHILD CARE

Question. Currently an estimated 11.6 million children spend a minimum of 10 hours per week in out-of-home child care. About 40% of American children under age 5 receive full or part-time child care. By the year 2000 it is estimated that more than 75% of mothers with children under six years of age will be working outside the home. Currently, there are no national standards or guidelines for the development or evaluation of child health and safety programs in child care centers or in family day care homes.

What child-care related public health activities has CDC participated in to date?

Answer. CDC recognizes the public health importance of infectious diseases, injuries and disabilities in out-of-home child care and is taking a lead role in prevention and control. We have made significant progress in collaboration with State and local health departments, universities, other federal agencies and the private sector to determine where and why children are at risk of disease and injury, develop and evaluate prevention strategies, and prepare guidelines for use by operators of child-care facilities, health care providers, and parents. Our efforts to determine the scope of infectious diseases, injuries and disabilities are focused on centers of more than 12 children, family group homes of 7-12 children, and family homes of 6 children or less in a large metropolitan area. We also are evaluating existing state regulations and practices for preventing infectious diseases and injuries and, in collaboration with the American Public Health Association (APHA) and American Academy of Pediatrics (AAP), are developing national performance standards for out-of-home child care.

Question. What level of resources have been provided and will be needed?

Answer. CDC is currently spending about $ 1 million to address the growing public health problems of diseases and injuries in child care. We believe that if resources were available, additional efforts could be devoted to expanding our studies of out-of-home child care facilities to include additional geographic areas, publishing and distributing the guidelines that are needed for disease and injury control, and develop the improved laboratory tests essential to rapidly and accurately diagnose many of the infectious diseases that are transmitted in the child care setting. However, CDC is not requesting additional funds for this purpose within the priorities of the 1991 budget, and no further offsets have been identified to accommodate such increases.

DISABILITY PREVENTION

Question. There are an estimated 35 million Americans with a disability with an estimated cost of disabilities is about $120 billion each year. We understand that persons with primary disabilities are at risk of developing complications or secondary disabilities that present additional health threats, and may, in some cases be of greater consequence than the primary disability. To address these concerns, in FY 1988, the Congress appropriated funds to establish a program for the prevention of disabilities.

How have these funds been utilized to date, what program priorities have been established, and what has been accomplished?

Answer. The CDC, in cooperation with the National Council on Disability, initiated a national program for the prevention of disabilities with the original FY 1988 appropriation of $3.83 million. Congress appropriated a similar amount in FY 1989 and increased the appropriation to $4.43 million in FY 1990. The goal of the program is to develop a national focus for the prevention of disabilities and to establish a strong intramural epidemiologic, surveillance, and coordination capacity at CDC. The national program also emphasizes providing technical and financial assistance to build capacity at the State and community levels to prevent disabilities. Moreover, the program includes developing a national information base to prevent secondary disabilities by providing technical and financial assistance to institutions to measure the effectiveness and cost of interventions.

The extramural program involves the use of cooperative agreements by CDC to conduct preventive interventions in three targeted disability groups: primary disabilities resulting from developmental disabilities; primary disabilities resulting from head and spinal cord trauma; and secondary disabilities. Secondary disabilities are complications that occur in persons with a primary disability that present an additional health threat that, in many cases, can be of greater health and economic consequence than the primary disability. To document the impact of disability on our national society, CDC contracted with the Institute of Medicine, National Academy of Sciences, to develop a national agenda for disabilities prevention.

To date, CDC has awarded cooperative agreements for capacity building to nine State-based projects and to four institutions as demonstration/epidemiology projects for the prevention of secondary disabilities. The CDC has provided technical assistance to these funded projects and to nonproject States to conduct prevention activities aimed at these three targeted disability groups. In addition, CDC has collaborated with other Federal agencies in implementing prevention activities.

Question. Since there is limited information as to the incidence, prevalence, and cost of disabilities, what has this program been able to do to gather appropriate data and form interactive alliances that will help to determine the focus and direction of prevention strategies at the national, State, and community levels?

Answer. The CDC recognized the limited data sources currently available in an effort to precisely measure the extent of the disabilities problem in this country. The CDC has stressed the establishment of surveillance both within the Federal agencies collaborating on disability issues and among the established cooperative agreement projects. The State-based projects all have a surveillance component within their respective offices of disability prevention. This requirement ensures that State projects develop and/or refine a systematic approach for collecting incidence, severity, prevalence, and economic data on targeted disabilities. This will lead toward epidemiologic data analysis and directed program actions geared toward prevention.

To date, the projects have identified a wide range of data sources and resources that are most valuable in the conduct of prevention activities. The analysis of critical surveillance information on developmental disabilities, head and spinal cord injuries, and secondary disabilities, and the prestige and policymaking efforts of established Advisory Councils are a key component of the State-based projects, CDC will conduct a program that provides mutual benefit to these cooperating agencies. More importantly, the focus of the program will be to maximize prevention strategies on the populations at risk or who have a disability.

Specifically, at the project level these networks have included such data: as high risk infant follow-up programs, head and brain trauma registries, spinal cord injury data bases, service inventories for education of children with special needs, birth defects and congenital anomalies registries, etc. At the Federal level, a wide range of data sources are used including: population based systems, census surveys, health interview data, disability benefits and population data, acute and long-term care cost data, special education enrollment information, and data gathered from Federally funded projects that provide services for persons with disabilities.

Question. What is the current level of interest and concern among States and prevention-oriented organizations and institutions regarding capacity development and participation in a national program for the prevention of disabilities?

Answer. When the original Program Announcement soliciting competitive applications for this program was announced in FY 1988, 26 States and 15 institutions submitted applications. Nine States and four institutions respectively were awarded cooperative agreements. This level of response was generated even in view of a limited response time for the preparation of applications. As the program developed national recognition through the support of the

National Council on Disability and through project workshops and conferences at the local, State, and national level, CDC came to recognize that the program has a high degree of visibility. With an increase in the FY 1990 appropriation to $4.43 million, CDC has already noted a large number of inquiries as to how this $600,000 increase might be utilized. Our plans are to award funds through a competitive announcement to address the prevention of secondary disabilities in selected populations, including a specific developmental disability and/or a specific chronic disease or condition.

Question. What would be the costs associated with the development of a program that would be national in scope?

Answer. Costs to develop a disabilities prevention program that would be national in scope and that would include 30-35 State or territory-based projects and 10-14 institutional projects would require an appropriation of approximately $20 million per year. However, CDC is not requesting additional funds for this purpose within the priorities of the 1991 budget, and no further offsets have been identified to accommodate such increases.

Question. Much has been said recently on the relation between infant mortality and poverty, particularly poverty among minority groups. We understand that black children are two times more likely to have a serious disability.

What do we know about the effects of poverty on children's physical and mental development?

Answer. We know that children from impoverished backgrounds are more likely to be considered mentally retarded when they reach school age. A CDC study has shown this in one large urban area in the southeastern United States. We are conducting studies to determine the causes of this gap. Areas of study that will receive particular attention include socioeconomic and environmental factors.

DEVELOPMENTAL DISABILITIES

Question. How common are developmental disabilities in the U.S. today?

Answer. The prevalence of disorders known as developmental disabilities is between 1 and 3 percent of the population. It is estimated that about 80,000 children are identified every year in the United States with a developmental disability and that there are over 4 million persons with a developmental disability. The combined Federal, State and local expenditures for developmental disabilities exceed $16.5 billion per year. The large majority of developmental disabilities is comprised of conditions that cause mental retardation. The most common known causes of mental retardation are Down Syndrome, Fetal Alcohol Syndrome and Fragile X Syndrome. Conditions associated with mental retardation can also be associated with one or more impairments limiting ambulation, hearing, vision, or communication. In 10 to 20 percent of developmental disabilities, the impairments responsible for disability do not include mental retardation. The cause of about half of all developmental disabilities is known, and CDC through its Disabilities Prevention Program has established collaborative projects and investigations that provide the basis for effective prevention programs. For the other half of the developmental disabilities where the cause is unknown, the CDC has assumed a leadership role in searching for specific causes of developmental disabilities from which prevention strategies can be formulated.

Question. What are CDC and the States doing to prevent developmental disabilities?

Answer: There are many State and Federal programs that support activities to previous developmental disabilities. It is not known how well these programs are actually preventing developmental disabilities. Preliminary studies at CDC suggest that the over all rate of mental retardation is too high. These studies do not yet permit the identification of the failures in prevention services responsible for this excess. The CDC Disabilities Prevention Program is trying to build the epidemiologic and management infrastructure in States to determine the rate of developmental disabilities by causes, both preventable and currently not preventable. Knowing in each state the rate of preventable developmental disabilities will provide the State the ability to identify its specific prevention gaps. The identification of these prevention gaps will be the lever to improve the use of currently available resources or point out the need for new resources. At the national level, CDC sponsored work has shown that Fetal Alcohol Syndrome costs the country about $10 billion a year. Since the cause of Fetal Alcohol Syndrome is known, just this one outcome represents a very substantial, national gap in the prevention of developmental disabilities. It is important to search for the other gaps in the prevention of developmental disabilities. CDC is building State capacity in epidemiology and management as a first step in improving our ability to prevent developmental disabilities.

RADIATION

Question. CDC is playing an expanded role in the effort to determine the health effects of radiation exposure and there is a growing concern about the health effects of such exposure in this country, particularly around nuclear facilities. There has also been an increased concern about exposure to indoor radon which is estimated to cause up to 20,000 lung cancer deaths per year. We are aware that CDC has a number of activities underway, some of which were mandated by Congress to look at these problems.

What radiation problems has CDC worked on?

What is your experience in this area?

Answer. The Centers for Environmental Health and Injury Control has provided technical assistance to States and Federal Agencies on indoor radon, and provides States with technical assistance to evaluate the possible health effects to populations exposed to radionuclides from nuclear facilities in proximity to the Tri-Cities in eastern Washington State (Hanford), Rocky Flats near Denver Colorado, and Fernald in Central Ohio. When requested, and if feasible, CDC performs epidemiologic studies of populations living in proximity to nuclear facilities. CDC also provides public health assistance when radiation emergencies occur, such as Three Mile Island. CDC has recognized technical experts in the fields of Radiation Epidemiology and Health Physics and is expanding its technical staff to address the growing public concern over possible health effects resulting from exposure to radiation.

Question. Does CDC have formal, designated responsibilities related to radiation, and if so, what resources have you had to carry out these responsibilities?

Answer: Yes, CDC has a number of designated responsibilities for radiation activities. These include the congressionally mandated study of thyroid disease morbidity around the Hanford Nuclear Reservation in the State of Washington, a Memorandum of Agreement with Department of Energy (DOE) to conduct a dosimetry reconstruction for the Fernald Feed Material Reprocessing Facility in Ohio, and CDC has been designated by PHS as lead agency with responsibility for planning and response to nuclear-related emergencies. CDC also has the responsibility to address such issues as radon which have an impact on the public health.

In order to fulfill our responsibilities related to radiation, CDC has established a Radiation Studies Branch. In FY 1990, $2.054 million was appropriated to CDC to conduct the Hanford thyroid morbidity study and for requisite scientific and management support for this study. In FY 1990, we expect that $540,000 will be provided to CDC via an Interagency Agreement with the Department of Energy to support the Fernald dosimetry reconstruction project. Additionally, approximately $75,000 is provided from CDC base funds to support other radition-related work, including indoor radon.

INJURY

Question. From information produced by CDC and others, it is our understanding that injury is one of the leading preventable public health problems in America today. We note that of over 150,000 injury deaths that occurred in 1986, over 52,000 were due to violence, nearly 48,000 were motor-vehicle related and an additional 40,000 deaths were from such causes as fires and burns, falls, drowning, and poisoning. One of every four U.S. residents is injured each year. Injury is the fourth leading cause of death and the leading cause of years of potential life lost. The burden of injury rests disproportionately among minority groups. In 1985, the lifetime cost of injury was estimated at $158 billion. We hear a lot about the problem of violence in this country and the disproportionate impact of violent crimes such as homicide on minorities.

Is this true, and if so, what are you doing about it?

Answer. Violence is indeed a serious public health problem in this country. Each year about 20,000 people die from homicide, making it the 12th leading cause of death. In 1985, homicides accounted for 5.2% of all years of potential life lost before age 65

(YPLL). Suicide, the 8th leading cause of death, results in approximately 30,000 deaths. Although great strides have been made in improving the health of the American people, a marked disparity remains in the burden of death and illness faced by blacks and other minorities relative to the majority white population. High rates of homicide mortality among blacks and other minorities account for much of this disparity. Homicide is the leading cause of death among blacks 15-34 years of age. For blacks overall, homicide is the third leading cause of years of potential life lost; for whites and persons of other races it is the sixth leading cause of YPLL. A black male has a lifetime probability of murder victimization of 1 in 28, compared to a white male probability of 1 in 164. In 1984, the homicide rate for blacks was 29.0 per 100,000. This rate was just over 5 times higher than the homicide rate for whites of 5.5 per 100,000. Although the homicide rate for black males 15-24 years of age has decreased 13% since 1978, the rate remains unacceptably high.

Because many kinds of injuries disproportionately affect minorities, most of the activities that are carried out by CDC's Injury Control Program to address the injury problem benefit minorities. However, CDC is also actively addressing the impact of violence on minorities. For example:

o CDC conducts homicide surveillance, and periodically reports figures on mortality and years of potential life lost. One major report published in 1986 focused on high-risk racial and ethnic groups. CDC will continue to monitor homicide rates for those groups, in accordance with the 1990 and Year 2000 Objectives for the Nation.

o Among extramural grants funded by CDC are a project in Kansas City to identify high-risk youth and adults who have been involved in violent disputes and provide them with conflict resolution skills training, and a cohort study in Houston and Baltimore to examine the problem of battered pregnant women.

o A descriptive evaluation of the increase in the numbers of youth homicides in Los Angeles is examining the higher rates found for Hispanics and blacks. **At the request of the Los Angeles County Department of Health Services and the Los Angeles Police Department, an analyses of various data sources with emphasis on gang involved youth homicides is being carried out. The purpose of the study is to identify trends, high-risk groups, and potential risk factors for youth and gang homicides in Los Angeles.**

o To identify the most promising homicide prevention measures available, a conference on violence intervention in minority communities is being sponsored by the Morehouse School of Medicine in collaboration with CDC. The conference will be held in the summer of 1990.

Question. I am told that injury is the leading cause of years of potential life lost. If this is the case, please explain how your budget request is consistent with the magnitude of the problem?

Why are firearm injuries a public health problem?

Answer. Injury is the leading cause of potential life loss between the ages of 1 and 65 and is clearly an important public health problem. Years of potential life lost between ages 1 and 65 from injury and violence exceed the years of life lost from the next two leading causes combined· cancer and heart disease. Because children and young adults, who would ordinarily be expected to have long lives ahead of them, are disproportionately affected by injury, the number of years of potential life lost due to injury is greater than the loss attributable to other more frequent causes of death that primarily affect older adults. However, it should be pointed out that injury is also a major health problem for older Americans. The Centers for Disease Control is building an injury control program that responds to the need to deal with injury as a major public health problem. This injury control program has grown rapidly in recent years to a level of $22.7 million in 1990. The 1991 budget request maintains this expanded level of support. Our comprehensive approach includes extramural and intramural research, technical assistance to governmental agencies and community based organizations, and State injury control program grants.

By any measure we choose, firearm injuries are a major public health problem:

- During the last 2 years for which data are available, 1985 and 1986, the number of people who died from firearm injuries in the United States (64,939) was greater than the number of fatal casualties suffered during the entire eight and a half year Vietnam conflict.
- Firearm mortality rates for females, male teenagers, and young adults have been higher during the 1980's than at any time previously.
- Injuries resulting from the use of firearms are the second leading cause of injury death in the United States.
- Estimates from 1985 indicate that for every fatality due to firearm injuries there are at least seven nonfatal injuries.
- In 1985 firearm injuries cost our society 14.4 billion dollars. The average per person cost for a fatality due to firearm injuries, $373,520, is the highest of any cause of injury.

INJURY INITIATIVES

Question. Several important reports dealing with the need to control intentional and unintentional injuries were developed by or for the Department of Health and Human Services during fiscal year 1989, including three Congressionally mandated reports. Please tell us what if any initiatives have been proposed by your agency to implement recommendations made in the following reports:

- Cost of Injury in the United States: A Report to Congress

- o Childhood Injuries in the United States (A Report for Congress)
- o Interagency Head Injury Task Force Report (A Report for Congress)
- o Report of the Secretary's Task Force on Youth Suicide
- o Injury Prevention: Meeting the Challenge (introduced by the Surgeon General)

Answer. The injury control program of the Centers for Disease Control played a substantive role in the development of each of the aforementioned reports. CDC has also taken action to ensure that injury control practitioners most interested in these reports will have access to copies of these documents. The documents dealing with injury prevention and the cost of injury were made available to the newly established Advisory Committee for Injury Prevention and Control. The other reports will be available for discussion during that Committee's March 1990 meeting. Recommendations made in these reports have had direct impact on program initiatives being developed and reviewed by our Agency. The injury control program is already undertaking a substantial amount of the work recommended in these reports. The 1991 budget request of $22.7 million maintains the 12% increase over 1989 provided to the injury control program by Congress in 1990.

Question. What progress, if any, has already been made towards implementing the recommendations made in these reports, what further progress can be made in fiscal year 1990 with funds already appropriated, and what further progress can be made in fiscal year 1991 with resources levels recommended in the Presidential budget for fiscal year 1991?

Answer. The five reports mentioned in the question above contain a wealth of recommendations for addressing the injury problem.

- o Recommendations in the Cost of Injury Report address four injury issues:
  - Injury Prevention and Control
  - Coding and Measurement
  - Data Needs
  - Treatment and Rehabilitation

CDC's Injury Control Program is taking a leadership role in coordinating and funding activities in most of these areas. For example, the recommendations for research have been incorporated in the Chapters of the Draft Year 2000 Health Objectives for the Nation on Unintentional Injury and Violence and Abusive Behavior. In addition, many of our research grants respond to some of the recommendations. To address some of the data needs we are developing a hospital trauma registry and working with other organizations to revise disease classifications to better describe injuries.

- Report to Congress on Childhood Injuries in the U.S.

  The report to Congress on childhood injuries pointed out that among children, 47% of injury deaths in 1986 were due to motor vehicle related injuries, 13% of childhood deaths are attributable to homicide-the second leading cause of injury death among children, fires and burns are the sixth major cause of injury death among persons below age 19-accounting for 7% of deaths, and almost 30% of childhood injury deaths result from head injury. Many of the CDC Injury Control program activities address these problems.

For example, CDC is involved with the Injury Prevention Research Center at the University of North Carolina in a study to determine risk factors for residential fire deaths in a predominantly rural State. We have funded other projects that address these problems as well.

- The report of the Secretary's Task Force on Youth Suicide contains recommendations on data development, evaluation research, service delivery and education. CDC's Injury Control Program is conducting several activities that address these recommendations. They include supporting injury surveillance projects which cover suicide and suicide attempts, developing a prototype suicide attempt surveillance system in Cobb County, Georgia; and participating with the New Jersey Department of Health in conducting a workshop to develop "CDC Recommendations for a Community Plan for Prevention and Containment of Suicide Clusters," and initiating a project entitled "Youth Suicide Evaluation: Program Descriptions, Evaluation Status, and Barriers to Implementation.

- The Interagency Task Force on Head Injury made recommendations on establishing Traumatic Brain Injury (TBI) as a reportable condition in federal systems, establishing working groups at the State and local levels to provide leadership and coordination of activities that would identify and assist persons with TBI, and the designation of a lead agency to assume responsibility for the coordination and planning efforts for federal, State, and private sector activities. The Injury Control Program has awarded grants to States and communities and research institutions to address these recommendations. For example, one of our researchers is working to develop methods to evaluate new treatments for acute head injury.

- Injury Prevention: Meeting-the Challenge provides not only background information on the extent of the injury problem, but is designed as a tool which will enable injury prevention and control practitioners to respond to the problem. Injury interventions are categorized in this report as "proven effective", "promising", "effective", or "insufficiently studied." All 15 State and Community-Based Injury Control Capacity Building grantees (WA, CA, OK, AK, NY, MD, RI, NC, MN, ND, CO, FL, MO, NYC, San Antonio) which were awarded in FY 89 have been supplied with this report and will use the information as they develop specific interventions. Each grantee plans between two and nine such interventions. Special attention is paid to those proven effective (e.g., bicycle helmets), but grantees are also encouraged to evaluate interventions performed in other categories as well.

BIRTH DEFECTS

Question. We understand that spina bifida and anencephaly are common birth defects that cause serious disability and contribute to infant mortality. About 3,000 children are born in America with spina bifida every year. Studies suggest that women who reported using multivitamins before pregnancy and during early pregnancy have about half the rate of spina bifida and anencephaly as women who did not report using multivitamins.

Why shouldn't we stop the research and recommend treating all women of reproductive age right now?

Answer. The current evidence does not permit us unambiguously to conclude whether the apparent protective effect of multivitamins results directly from multivitamin use or from other characteristics of women who use vitamins. Until there is clear evidence that periconceptional supplementation with multivitamins prevents spina bifida, we should not supplement all women of reproductive age because there is a risk that such supplementation could have adverse side effects. Some vitamins, in high doses, are believed to be harmful to fetuses. Until there is proven efficacy, we cannot justify the risk or cost of wide spread multivitamin supplementation.

Question. We understand that recently a group of experts in the field of spina bifida met to develop a research agenda to find the cause of spina bifida. What were their recommendations?

Answer. The Spina Bifida Association of America with the assistance of the Nemours Foundation, CDC, and NIH convened a workshop of leading scientists concerned with finding the causes of spina bifida. The purpose of the meeting was to develop a national research agenda to find the causes and ways to prevent spina bifida. The group recommended research in three areas: epidemiologic, biochemical, and developmental biology studies. In the area of epidemiology, a randomized clinical trial of the use of periconceptional multivitamins to prevent spina bifida and anencephaly in the general population was recommended. For biochemical studies it was suggested that studies should focus on the role of folic acid and other nutrients in the development of the neural tube. In the area of developmental biology, it was suggested that animal models should be developed to advance the understanding of the developmental process that leads to a neural tube defect.

Question. The option of conducting a clinical trial of multivitamin use in areas of high rates of spina bifida has been discussed for sometime. Why should a clinical trial be conducted?

Answer. Spina bifida is one of the most common and disabling of birth defects. Spina bifida is a birth defect that comes in epidemics which means that some environmental factor or factors are responsible for the epidemics. Except for African Americans, the rates of spina bifida increase with lower social class, another indication of environmental causation. The best evidence today suggests that the environmental factor or factors are nutritional. Early in the 1980s, English scientists published a study suggesting that supplementation with multivitamins before and shortly after conception may lower by 7 fold the rate of spina bifida among women who had previously had an infant with spina bifida. The study was not a randomized clinical trial, thus it is possible that the preventive factor was not the vitamins themselves but rather some other environmental factor in the lives of women who took the vitamins. Thus there was insufficient evidence upon which to make a policy of supplementation for these high risk women.

Most infants with spina bifida are born to women who have never had a child with spina bifida. In the last 18 months there have been 4 papers published studying the relationship between nutrition and spina bifida among women who have never had an infant with spina bifida. None of these studies was a randomized clinical trial. Three of these studies suggested that nutritional factors were very important in the etiology of spina bifida and one was a negative study. The negative study was the NICHD sponsored study of women from California and Illinois. Most of the women were from California. California has the lowest rate of spina bifida in the world.

The three positive studies were from intermediate risk areas. One was the CDC study of Atlanta women, one was the NINCDS sponsored study of women from Boston and one was of Perth, Australia women. None of these studies was a randomized clinical trial, thus the protective environmental factor may have been another environmental factor in the lives of women who took vitamins rather than the vitamins themselves.

If spina bifida could be prevented by multivitamin supplementation, it would represent one of the truly great accomplishments in the prevention of disease and disability. Even though vitamins are generally regarded as safe and some members of the public are beginning to call for universal supplementation of women of reproductive age, CDC does not think that the current efficacy data are sufficiently strong to recommend undertaking the possible risk and cost that would accompany a PHS policy to supplement all women of reproductive age.

CDC does think that it is a high priority to do the research that would provide the data to settle the efficacy issue. The best way to settle the efficacy question is to perform randomized clinical trials in high risk areas. CDC is currently implementing a feasibility study for such a trial.

The Spina Bifida Association of America sponsored in December a conference to determine the research agenda to find the causes of spina bifida. Leading scientists from around the world were present. This group strongly recommended research to determine whether or not multivitamin supplementation will prevent spina bifida.

BIRTH DEFECTS-CRACK COCAINE

Question. Cocaine in the form of "crack" is cheap and readily available to all segments of the U.S. population, including women of childbearing ages. We heard reports that for the year 1989, more than 400,000 babies--or 11% of all babies born in the U.S. that year--were exposed to cocaine.

Is there an epidemic of birth defects caused by the spreading use of crack cocaine?

Answer. It is clear that cocaine use during pregnancy can create serious health problems for both the mother and the infant. Women who use cocaine during pregnancy have an increased rate of stillbirths and spontaneous abortions. Specifically, the use of cocaine during pregnancy can lead up to a seven-fold increase in abruptio placenta, which is the premature separation of the normally implanted placenta. This complication of pregnancy is associated with an increased maternal, fetal, and neonatal mortality. Infants who are exposed to cocaine prenatally often experience transient and long-term neurobehavioral effects and neurological abnormalities which many times require intensive care after birth and a prolonged hospital stay. A CDC study and others conducted throughout the country suggest that women who use cocaine may be at higher risk for having babies with certain birth defects, like renal and brain abnormalities. Although at this time we cannot pinpoint what proportion of birth defects are caused by cocaine, the health problems related to the use of cocaine during pregnancy pose serious health threats to the health of women and children nationwide, and should be addressed so prevention strategies can be developed and applied. The CDC is developing initiatives to address this issue.

FETAL ALCOHOL SYNDROME

Question. We understand that the use of alcohol during pregnancy can lead to fetal alcohol syndrome, a condition that causes stunted growth retardation, mental retardation, and other developmental disabilities.

How frequent is fetal alcohol syndrome in the U.S. today?

Answer. In 1988, the CDC's Birth Defects Monitoring Program found that 3 to 4 of every 10,000 babies born in America had the fetal alcohol syndrome, or as many health professionals call it FAS. This would represent between 1,000 to 1,300 babies born with FAS every year. These figures, however, do not tell the whole story. There are significant differences in the rate of FAS among minority groups. FAS is 30 times more common among Native Americans babies than whites and 6 times more common among blacks. There is also the problem of diagnosis. Many children with FAS are not diagnosed during the first few days of life. FAS, especially in milder forms, is not recognized equally well by all healthcare providers, and some are reluctant to "label" infants as having FAS, and mothers as being "alcoholic." Only when they show some type of developmental disability that the diagnosis is considered or confirmed. We estimate that as many as 6,000 babies are born every year with FAS or some effect from the mothers use of alcohol during pregnancy.

BIRTH DEFECTS

Question. We know that birth defects is the major cause of infant mortality in America and a major contributor to developmental disabilities. We also know that each year about 3% of all babies are born with a serious birth defect. That is, over 110,000 babies every year born with a serious deformity. The States are responsible for providing services to children with disability associated with congenital malformations.

Do State health departments need assistance in order to be able to assess the health impact of congenital diseases?

Answer. There is increased recognition within State health departments of the importance and impact of congenital malformations. Congenital malformations are the leading cause of infant mortality in the U.S. and in most States. The States are responsible for providing services to children who experience morbidity and disability associated with congenital malformations. The other recent demand on States is the need for surveillance for congenital malformations and their potential association with exposure to hazardous substances in the environment. To address these needs, over 30 States are expanding their activities in the design, implementation and operation of birth defect surveillance programs. Currently, the Division of Birth Defects and Developmental Disabilities is providing technical assistance through cooperative agreements with three States, annual workshops and conferences, and technical assistance on surveillance methodologies. The States on numerous occasions have requested additional resources be made available to the States in the form of additional funds and technical expertise. States with birth defects programs have asked CDC to develop a technical assistance focus on adverse reproductive outcome surveillance methodology.

Part of the $11.5 million increase requested in 1991 for CDC's components of the PHS-wide Infant Mortality Initiative will be used for such surveillance and technical assistance activities.

LOW BIRTH WEIGHT

Question. We know that the United States has a high infant mortality compared to other developed countries and that low birth weight as in prematurity is a major reason for this difference. We also understand that smoking and alcohol use during pregnancy may be important causes of low birth weight.

What is CDC doing to find other causes of low birth weight and its prevention?

Answer. The Centers for Disease Control (CDC) provides the Public Health Service with leadership for surveillance and epidemiologic assistance for infant health issues. The CDC is the lead agency for surveillance and related technical assistance, both national (through the National Center for Health Statistics) and State-based surveillance, in the area of infant health.

The CDC's mission includes providing new information and developing and testing methods to further reduce infant mortality. Within its mission to prevent unnecessary deaths, disease, and disability, CDC has identified five key issues that are critical to the reduction of infant mortality related to low birth weight.

- If all women were to receive adequate prenatal care, the incidence of low birth weight could be lowered. (Estimated 9-12%)
- The prevalence of low birth weight babies could also be reduced if all smoking during pregnancy were eliminated. (Up to 25%)
- Low birth weight could be reduced if all pregnant women with borderline or frank anemia received iron supplementation. (Est. 5-9%)
- Both white and black low birth weight and much infant mortality could be prevented if all couples could choose the timing of their giving birth. (Est. of 6% and 16% of white and black LBW and 10% of IM)
- Postneonatal mortality could be substantially reduced through control of preventable causes such as infection and injuries.

After the successful application of known interventions, the black/white gap in low birth weight and infant mortality should be greatly diminished. However, racial and ethnic disparities in low birth weight and infant mortality are not completely understood, and more epidemiologic research needs to focus on identifying the next generation of interventions, especially those designed to reach populations not currently being served.

- CDC is sponsoring a study being conducted by the Morehouse School of Medicine to develop a better understanding of the black/white gap in low birth weight among college graduates. Preliminary findings indicate that:
  - Despite almost universal receipt of early prenatal care with obstetrician/gynecologists, black college graduates were at twice the risk of delivering a first child with low birth weight as were white college graduates.
  - Noted discrepancies in income and marital status apparently do not explain the low birth weight risk. Further follow up of a sample of these women is ongoing, to determine whether content of prenatal care, extent of maternal morbidity, or behavioral risks such as stress, lack of social supports, smoking, or alcohol consumption can help to explain the gap.

With part of the additional $11.5 million in Infant Health Initiative funds requested for FY 1991, CDC plans to pursue the leads from this study with additional multidisciplinary, epidemiologic research into the black/white differences in low birth weight.

One area which we have only begun to explore is the potential impact of environmental factors on birth weight and prematurity. A partnership between CDC and the State of Georgia funded by the Agency for Toxic Substances and Disease Registries has been studying whether a variety of environmental exposures cause very low birth weight (birth weight of 1500 grams or less). These factors include exposures from the environment, occupational exposures and household exposures. Learning what causes very low birth weight provides new means to prevent this serious and common problem in American children.

TOBACCO

Question. I understand that the death rate from lung cancer is going up dramatically in women, but not in men.

What is the CDC doing about this epidemic?

Answer. Lung cancer is the leading cause of cancer death in the United States. In men, the death rate for lung cancer is almost three times higher than that of colon cancer, the next most common cancer in men. Lung cancer now surpasses breast cancer as the leading cause of cancer death in women. Smoking causes nearly 90% of all lung cancer deaths, resulting in approximately 106,000 lung cancer deaths each year.

The CDC's Office on Smoking and Health (OSH) has the Department of Health and Human Services' overall lead for tobacco and health activities and is responsible for coordinating U.S. efforts to reduce tobacco consumption. The Office provides researchers with ongoing technical and scientific support. In addition, the Office coordinates information to assist other health organizations, most notably State health departments, in public health prevention and cessation efforts. Surveys of adults and adolescents are performed and analyzed to better understand the trends in smoking prevalence and the reasons why young people begin to smoke and why older people quit smoking.

The Office also conducts a national public information campaign, with special emphasis on adult and young women. This health education campaign against smoking, that began after the release of the first Surgeon General's report in 1964, has led to a 28% reduction in the prevalence of smoking in America (from 40% in 1965 to 29% in 1987). The Office on Smoking and Health has published Surgeon General's reports since 1964. As a major part of its education campaign, the Office produces media spots for television, radio, and newspapers and other print materials that are used globally.

The CDC also sponsors the Smoking Cessation in Pregnancy (SCIP) project. The SCIP project has focused on translating controlled research results into the prenatal clinic and WIC service routines on a continuous basis, while relying exclusively on existing staff to counsel and educate patients in smoking cessation. Intervention strategies and materials, based on the results of focus groups from prenatal populations, were generated through the SCIP project.

In addition, CDC works with State and Territorial education agencies, national organizations, and other youth-serving agencies to help schools develop, evaluate, and improve health education programs that address a full range of health risk behaviors among youth, which include smoking. CDC's evaluation demonstrated that comprehensive school health education is an effective means of helping children improve their health knowledge and attitudes and decreasing the likelihood that they will adopt unhealthy behaviors like smoking.

Question. Can more be done?

Answer. There are always more scientific opportunities than resources to support them. If additional funds were available, further efforts could be taken to:

- o Strengthen the capability of CDC to educate the public and professional communities about the health consequences of smoking for women.
- o Expand assistance to States, voluntary health agencies, and national leadership groups to strengthen or develop tobacco use prevention programs, especially among teens, young women, and minorities.
- o Expand the Office on Smoking and Health's capability to provide technical services to the general public and the scientific and public health communities.
- o Establish an ongoing national surveillance effort to track and analyze female tobacco-related behavior and illnesses among the population, including teenagers and high-risk groups.
- o Establish comprehensive school health programs for all students K-12 in our nation's schools.
- o Establish feasible and effective models by which workplace smoking policies and smoking cessation services can be successfully provided for small, medium, and large businesses.
- o Expand the current SCIP project beyond the three initial demonstration States to a nationwide program in which technical assistance would be offered to all States. Part of the $11.5 million increase proposed in 1991 for CDC's component of the PHS Infant Mortality Initiative would be used to expand SCIP projects to 7 additional States, for a total of 10 State porgrams.

Question. Lung cancer rates are much higher in blacks than in whites. It is said that this is due to the higher smoking rates among blacks, particularly among black males.

What is CDC doing to reduce smoking rates among blacks?

Answer. Since 1979, the Office on Smoking and Health has carried on a continuing program to inform the American public of the hazard of cigarette smoking. During these past 10 years the Office has targeted a number of its information efforts to minority audiences. Television spots have been produced to reach minorities. For example, television spots have been produced in various Spanish dialects (Mexican, Cuban, Puerto Rican) and marketed to Spanish speaking TV stations. Another example is seen in a spot produced using popular black basketball stars to reach young black men. A variety of radio spots using popular black and Hispanic artists have also been produced and marketed to ethnic stations. Print ads aimed at black women as well as Hispanic and black youths have been distributed to women's magazines and school newspapers.

The National Advisory Committee, chaired by the Surgeon General, devoted one of its meetings to cover the issue of smoking and its impact on minority populations. As a result, the Roundtable on Smoking and Minorities was established to address this issue. In addition, the Office is exploring opportunities to work creatively with minority media professionals and others who work with minority groups.

Question. And what more could be done?

Answer. There are always more scientific opportunities than resources to support them. If additional funds were available, further efforts could be taken to:

- o Carry out targeted public education messages to minority groups at risk.
- o Emphasize the importance of comprehensive school health programs, particularly in minority communities.
- o Continue to provide leadership and technical assistance to States and 40 voluntary associations that are responding to this public health problem.

SMOKING/YOUTH PREVENTION

Question. Smoking rates have declined steadily in the United States during the past 25 years. Nevertheless, more than 50 million Americans continue to smoke, and most disappointingly, more than 3,000 teenagers begin to smoke each day.

If our progress in reducing smoking is to continue--and hopefully, accelerate--don't we need to place more emphasis on preventing the onset of smoking in children and adolescents?

Answer: Approximately 16 percent of high school senior boys and 20 percent of high school senior girls smoke cigarettes. Over half of all smokers start before they are eighteen and nearly 90% begin before they are 21. Many young people may underestimate the addictive nature of smoking. Given the impact of maternal smoking on newborn babies, it is even more important that the proportion of high school girls that smokes begins to decline.

In reaching teenagers, we are concerned with those who smoke cigarettes or are likely to become adult smokers. Smokers and potential smokers are a very different population from the group who will never be smokers. For the most part, they are children from blue-collar families, they are less academically oriented, they may be precocious sexually and in other ways, and they are more apt to be employed outside of school hours with their own incomes.

Lloyd Johnston of the University of Michigan's Institute for Social Research described these young people, based on his organization's 10-year study of drug use among American high school seniors. Here are some of the characteristics of teenage cigarette smokers cited by Johnston:

- Of those who reported daily smoking by senior year, 57% began smoking by age 14.
- Of the seniors who smoked half-a-pack or more a day, 53% said they had already tried to quit and failed.
- Only 7% of students with an A-average in their senior year were daily smokers. In contrast, 47% of students with a D-average were daily smokers.
- Of high school seniors who smoked half-a-pack or more a day, 95% had used an illicit drug and 81% had used an illicit drug other than marijuana. Current marijuana use was 8 times as high among pack-a-day smokers as among nonsmokers, and daily marijuana use was 20 times as high.

Youth most likely to smoke are the hardest to reach through formal school curricula and through written communications. The corollary is that they are also the ones most susceptible to visual imagery. Research has shown television, radio, and display advertising to be the preferred media to reach this population.

Question. What is CDC doing?

Answer. It is the mission of CDC's Office on Smoking and Health (OSH) to prevent death, disease, and disability caused by tobacco use and to coordinate a national program to reduce the prevalence of tobacco use in the overall population, as well as in specific target groups such as teenagers. The CDC is conducting a national prevalence survey and special analyses of teenage smoking behavior, as well as targeting specific information activities to reach this audience. During these past 10 years, OSH has targeted a number of its information efforts to teenage audiences: television, radio, and printed material have been produced and widely distributed.

In addition, CDC works with State and Territorial education agencies, national organizations, and other youth-serving agencies to help schools develop, evaluate, and improve health education programs that address a full range of health risk behaviors among youth, which include smoking.

DIABETES

Question. Diabetes is a common and serious health problem in the United States, and I understand that those people who may be least capable of dealing with their diabetes--minorities such as blacks, Native Americans, and Hispanics, the elderly, and others who are under-insured--have a much higher rate of diabetes and its complications.

What are you doing to deal with these problems?

Answer. There are presently about 7 million persons with diabetes in the United States. You are correct that minorities, the elderly, and other medically underserved populations are affected disproportionately by diabetes and its complications. Diabetes incidence rates are twice as high among Hispanics and Native Americans as they are among white Americans. Mortality rates due to diabetes are twice as high among black females as among white females, and 40 percent higher among black males than among white males. Furthermore, minorities bear a disproportionate burden of diabetes complications. End-stage renal disease due to diabetes, for example, affects 6 times as many Hispanic and 60 percent more black and Native American diabetics as white diabetics. Rates of diabetic eye disease are three times as high among Hispanics as among white Americans.

The CDC is presently working with State health departments and others to improve the surveillance of these health problems, so that their distribution among specific population groups can be better defined.

Several components of the Public Health Service have joined recently with organizations outside of Government in sponsoring conferences that addressed the problem of diabetes in the black population. This spring, CDC is cosponsoring a conference in San Antonio, Texas, that focuses on diabetes among Mexican-Americans.

In addition, CDC is asking States to address issues related to diabetes in minorities in their applications for funding of their state-based diabetes control programs, to be submitted this year. For example, we need better diabetes surveillance in Hispanic and other minority populations, and increased emphasis by the state-based control programs on these high-risk groups. CDC is also planning to demonstrate the application of new program techniques in "diabetes translation communities," preliminary to the widespread implementation of those techniques found most effective.

COMPREHENSIVE SCHOOL HEALTH EDUCATION

Question. Last year this Committee gave CDC $3.5 million to begin comprehensive school health education.

Please tell us what progress has been made?

Answer. The CDC has been working with national organizations, and State and local education agencies to help schools implement comprehensive school health education programs.

- All 55 State and Territorial education agencies and 16 local education agencies that receive financial and technical support from CDC have employed staff and are implementing programs designed to help schools develop comprehensive school health education and HIV education programs.

- All 55 State and Territorial education agencies and 16 local education agencies are training teachers to educate their students about comprehensive school health and HIV. For example, as of May 1, 1989, the New York State Department of Education trained over 12,200 teachers, school administrators, school board members and parents.
- Thirteen regional teacher training centers that focus on comprehensive school health education have been established. These centers are operated by departments of education and health, universities, and other associated organizations. Over 10,000 individuals from more than 20 States have been trained by these centers. By the end of the fiscal year, over 30 centers will be providing training.
- By the end of the fiscal year, a prominent national organization will receive financial and technical support to disseminate validated comprehensive school health curricula to educators across the country.

Question. How will we know if such efforts are effective or not?

Answer. The CDC has established a Youth Risk Behavior Surveillance System that will provide information about the incidence and prevalence of six important adolescent risk behaviors: alcohol and drug abuse, tobacco use, sexual behaviors and unintended pregnancies, dietary behaviors, and behaviors that result in injuries.

In addition, CDC will monitor on a nationwide basis the expansion of comprehensive school health education programs in the Nation's schools. The information gained from monitoring these important health risk behaviors will allow States to assess the effectiveness, over time, of comprehensive school health programs.

Question. Is there anything this committee can do to support comprehensive school health education programs?

Answer. The Committee's action to target comprehensive approaches in the FY 1990 budget reflects a clear understanding of the value of comprehensive health education strategies in schools. The Presidential Commission on the Human Immunodeficiency Virus Epidemic reviewed this issue in their final report: "The Commission strongly believes that the introduction of an age-appropriate comprehensive health education curriculum that encompasses grades K through 12 is long overdue. Providing our nation's school children with education about HIV transmission . . . is a significant step. However, it represents only a stop-gap measure to correct a larger problem." The Commission went on to recommend: "All schools, both public and private, should have comprehensive health education programs for grades K through 12 fully implemented by the year 2000."

INFANT HEALTH

Question. We understand that there are large differences in infant mortality rates between different populations, with minority communities suffering the most. You requested $11.5 million in new resources for CDC work in infant mortality.

Can you explain how this work can be expected to help solve the problem of so high an infant mortality rate, especially among minorities?

Answer. The CDC has estimated that at least 30% of infant deaths could be prevented if this nation were to implement what we know will work. The failure to meet the 1990 Prevention Objectives for Infant Mortality and to reduce the unacceptable gap between black and white infants' survival was due in part to the States' lack of sufficient data and statistical and epidemiological capacity to target existing resources, to develop new interventions, and to monitor program impact. At present, State maternal and child health (MCH) programs have little access to surveillance expertise and analytic capability--areas of CDC leadership. Existing surveillance activities in States are incomplete and do not permit State-to-State comparisons, adequate linkage to national surveillance efforts, or appropriate monitoring of quality control issues.

To help States better address this health issue, CDC has developed and initiated a comprehensive mechanism to:

- Identify those populations at highest risk

- Enable States to target their intervention efforts

- Provide resources for evaluating progress toward the Year 2000 objectives related to maternal and infant health.

Infant mortality prevention activities at CDC are an integrated effort including surveillance, epidemiologic studies, technical assistance to State health agency personnel, and limited direct research targeted to the reduction of perinatal, neonatal, and postneonatal mortality and morbidity related to low birth weight, sudden infant death syndrome (SIDS), congenital anomalies, prematurity, complications of pregnancy, and major nutrition-related health problems in infants and pregnant women.

In this partnership with States, efforts are directed toward reducing adverse pregnancy outcomes in defined high-risk groups (Blacks, Native Americans, etc.) by identifying behavioral risk factors (e.g., smoking, alcohol use, etc.) and developing and evaluating relevant interventions.

Question. Is this all the assistance that States will need to implement those programs to carry out the infant mortality health mission?

Answer. We plan to expand this program to enhance MCH surveillance and epidemiologic assistance efforts in the States. With the requested funds, CDC will work in the following areas to further address the problem of high infant mortality rates:

- We can provide enhanced State-based surveillance to an additional 10 States for a total of 18 States. Additionally, four States with high infant mortality rates will be targeted for extensive assistance with in-State placement of technical personnel to build the State's capacity for MCH epidemiology. Birth and death certificates will be linked to key programs such as Medicaid and WIC, to monitor program effectiveness in preventing low birth weight, including program coverage and targeting. Such intensive epidemiologic assistance has been provided to South Carolina, Alabama, and Georgia through assignment of MCH epidemiologists in collaboration with the Health Resources and Services Administration and the States.

- Other States will receive epidemiologic analytic assistance aimed at understanding the sources of black/white discrepancy in low birth weight and infant mortality, especially as related to behavioral risks amenable to intervention and access/utilization of services.

- A specific concern is eliminating maternal smoking. Over 900,000 children are born each year to women who smoke, a practice that doubles the risk of LBW and increases the risk of stillbirth or neonatal death by up to 100%. Maternal smoking accounts for 2,500 to 3,500 infant deaths each year. Cessation of health risk behaviors can have a positive effect on birth outcome. The CDC has launched a demonstration project in three States to develop effective Smoking Cessation in Pregnancy (SCIP) interventions for women receiving publicly-funded prenatal care.

  Assistance has been provided to additional interested States for widespread dissemination of smoking cessation programs for high-risk, low-income, pregnant women, and this program will be expanded with the new funds in 1991 from 4 States to a total of 20 States. State personnel will be trained to implement smoking cessation programs in public prenatal and WIC clinics and to monitor the quit rates and prevention of low birth weight in the recipients.

INTERNATIONAL HEALTH

Question. CDC's domestic mission includes strengthening the capacity of State and local health departments to deal with public health problems.

Is there a comparable effort on the international scene?

Answer. CDC provides assistance in two main areas which strengthen the capacities of Ministries of Health in foreign countries. First, CDC collaborates with field epidemiology training programs modeled closely on the CDC's Epidemic Intelligence Service program designed to train epidemiologists to deal with a broad range of public health issues within their own developing environments. Second, staff working with national counterparts in collaborative projects in developing countries do much to strengthen surveillance and management systems as part of their routine activities. Both processes leave a sustainable force within the Ministries and supplement short term technical assistance which may deal with specific problems on a one time basis.

Question. Why should CDC be interested in international health issues?

Answer. CDC is currently the lead agency within the Public Health Service capable of providing technical assistance on a broad range of disease prevention and health promotion issues.

Our national issues are not unique to the United States and our ability to provide this advice and assistance is widely recognized beyond our borders. CDC's ability to provide the right assistance in a timely manner has done much to improve the health of the people of the World while bringing credit to the Public Health Service in particular, and the U.S. in general.

As the world grows smaller through improved travel and communications, CDC's relative strengths in health information, infectious and chronic disease prevention and control, environment and work place health issues, and injury prevention can continue to be an important force in the U.S.'s contribution to global development.

LYME DISEASE

Question. It is this committee's understanding that Lyme disease is now one of the most important emerging diseases of this decade; we are informed that more than 7,000 cases were reported in 1989 and that more than 20,000 cases have been reported to date.

What are you doing to combat this disease?

Answer. The Centers for Disease Control has initiated a broad-based program on Lyme disease with the goal of decreasing incidence of disease in areas such as the northeastern states, where the disease currently occurs, and preventing spread of disease to areas not now infected. The CDC program is designed to define more accurately the distribution of the disease, develop better diagnostic tests that can be standardized, develop more effective prevention and control strategies based on tick control and environmental management, and educate the lay and medical communities about this disease. In 1991, CDC expects to devote about $2 million to these Lyme Disease activities.

FOODBORNE DISEASE

Question. We understand that even with the push to improve the quality of foods and food handling, millions of cases of foodborne diseases and about 9000 deaths from them occur in our country each year.

What is being done to identify the major sources of food contamination and other causes of these diseases, and what is being done to prevent or control foodborne diseases?

Answer. To identify the major sources of food contamination and behavioral factors which contribute to foodborne disease, CDC conducts surveillance of foodborne disease, identifies foodborne disease problems, and investigates to determine the causes and contributing factors. CDC works with Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), National Marine and Fisheries Services (NMFS), the States and universities, and industry to develop and evaluate control methods.

Recently, CDC has identified eggs from infected chickens as the source of a massive increase in Salmonella enteritidis infections in the United States. Efforts by USDA, FDA, and the States, and industry have discovered that two devastating illnesses, hemolytic uremic syndrome in children and thrombotic thrombocytopenic purpura in adults, are caused by a newly recognized foodborne pathogen, Escherichia coli 0157:H7, which has a reservior in cattle and infects humans primarily through eating undercooked hamburger. Another important effort has shown that most Vibrio vulnificus systemic infections, which have a mortality rate of 50 percent, are caused by eating raw oysters, leading to recommendations that immunocompromized people should not eat raw oysters.

DENGUE/DENGUE HEMORRHAGIC FEVER

Question. We understand that several hemorrhagic fevers are occurring with greater frequency in United States. Dengue hemorrhagic fever has become a major increasing problem in Puerto Rico since the first cases of this devastating disease were reported in 1985. We are advised that this disease may move into the United States with greater frequency and that other virulent hemorrhagic diseases, once extremely rare or unknown here, have recently been reported.

How are reported cases of these diseases managed in the United States?

Answer. Imported cases of confirmed dengue are occurring with increasing frequency in travelers returning to the United States after visiting tropical areas that are endemic for the disease, including Puerto Rico and the U.S. Virgin Islands.

The disease is not reportable in the U.S.; cases are usually managed by infectious disease experts who are called in to consult, usually after the patient has been hospitalized. CDC personnel maintain routine passive surveillance for dengue/dengue hemorrhagic fever in the U.S. and, during times of increased risk, initiate active surveillance in those areas where the vector mosquitoes occur.

Question. Are current recommendations adequate to prevent transmission of these diseases in this country?

Answer. The principal vector mosquito of dengue viruses, Aedes aegypti, occurs throughout the Gulf Coast states from Texas to Florida. A secondary vector, Aedes albopictus, was introduced into the United States in 1985 and has now spread to 17 states, including some states in the north central part of the country. Mosquito control has traditionally been the responsibility of the states.

However, CDC provides training and consultation on prevention and control of these mosquitoes to state health departments and has been active in conducting research to develop more effective control methodologies.

IMPROVING THE TIMELINESS OF NCHS DATA

The Administration request for CDC describes major new needs for data on the Year 2000 Health Objectives for the nation, minorities, the aging, the family, and for targeting scarce resources. Yet your budget for health statistics hasn't grown.

Question. Do you feel that you are able to meet the data needs you describe with this level of funding?

Answer. The CDC and NCHS will take steps to ensure that the Nation's highest priority health care data requirements are supported.

In FY 1990 the Committee expected that NCHS fully fund all components of the vital statistics system including birth, death, fetal death, marriage and divoarce, induced termination of pregnancy, and the program to link birth and infant death records.

Question. Have you complied with this and does the budget request contain funds to collect data on these same components in FY 1991.

Answer. In FY 1990 we have fully funded the vital statistics system including birth, death, fetal death, marriage and divorce, induced termination of pregnancy, and the program to link birth and infant death records. In FY 1991 we anticipate that all of these components will be continued.

Question. You've talked to us before about efforts to improve the timeliness of data through automation of NCHS programs. What is the administration proposing to address this crisis?

Answer. NCHS has continued to make strides in improving the timeliness of data release. Over the last several years, the backlog in release of vital statistics has been eliminated. This has been accomplished by virtually cutting the publication process time in half. Other surveys have made similar improvements.

Automation as it directly relates to the improvement in timeliness of our data continues to be of highest priority in NCHS Our recent and highly successful automation of data collection for our NHANES III survey convinces us that we must eventually automate all our surveys. We have several automation projects currently underway that will have a significant impact on the timeliness, quality and ease of use of our data. For example, we are currently developing:

- o A medical coding system on microcomputers that will provide for the automation of the collection of mortality data. Such a system will greatly contribute to both the quality and the timeliness of mortality data and will insure national data are available at the same time as state and local data.

- An automated personal interviewing system on laptop computers for all our personal interview surveys. Such automation will not only speed the availability of our survey data, but also allow us to quickly modify the content of the survey in order to measure a fast breaking point.

USE OF EVALUATION FUNDS BY NCHS

Question. Approximately 30% of your FY 1991 request is composed of evaluation funds and seems to be increasing each year as a source of funds. Why are you relying on evaluation funds rather than requesting the funds in your budget?

Answer. Since NCHS data is used to evaluate a variety of public health programs sponsored in part by each of the PHS agencies, this source was deemed to be appropriate in view of the overall budget constraints. The $19 million of 1% evaluation funds requested to be directed to NCHS surveys in 1991 is the same level as provided by Congress in 1990.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

Immunization Rates

Question. There are still reports that immunization rates among pre-schoolers in some inner-city areas are alarmingly low. The FY 1990 appropriation for the immunization program included funds for outreach demonstrations to reach these pre-schoolers. Please provide the subcommittee an update on this outreach effort. What percentage of proposed projects will you be able to fund in FY 90?

Answer. Vaccine coverage by age 2 against individual diseases is believed to range between 70-80 percent; however, enecdotal information suggests that in some inner city areas vaccine coverage may be as low as 50 percent. Because of our concern about these low immunization levels and the increase in measles in this age group, nine small demonstration projects were funded in FY 1989. Six of these projects are for evaluating the impact of implementing recommended policies and procedures and the impact of using new and unusual approaches to improving immunization levels. Approaches being funded include using motivational incentives for high risk children and providing immunizations within the hospital as an effective source of vaccine delivery. The remaining three projects are to demonstrate the accuracy of different methods of assessing immunization levels among preschool children. These demonstrations will be continued in FY 1990.

Funds appropriated in FY 1990 for outreach demonstration will be used to conduct larger in-depth demonstrations and will focus more directly on identifying intervention activities which can be applied to multiple inner city areas. It is anticipated that three to five of these new demonstrations will be initiated in FY 1990. In addition these new funds will be used to:

1. Conduct intensive program reviews in States with excessive disease morbidity among preschool children.
2. Collaborate with other federal agencies, such as the Department of Agriculture's Women, Infants and Children (WIC) program, to insure that opportunities for immunizations are being used.
3. Collaborate with private organizations such as "Healthy Mothers - Healthy Babies" to focus their interest and their resources toward immunization.
4. Develop standardized guidelines for conducting immunization level assessments of specific population sub-groups.
5. Obtain a national estimate of vaccination coverage among preschool children.
6. Increase the use of recommended policies and procedures in areas of excessive preschool morbidity by providing refresher training courses for public health providers.
7. Increase consumer demand for immunizations through special contracts with community-based organizations to evaluate cost-effective approaches to increase demand.
8. Attempt to determine why lower socio-economic groups do not use immunization services and develop effective interventions.
9. Evaluate the cost-effectiveness of clinic-based education, the use of incentives, public service announcements, and the use of outreach workers.
10. Develop reliable, population-based method for measuring current immunization levels.

Polio Eradication

Question. I understand the CDC has expertise to contribute to the control of polio in the developing world. What level of funding would be necessary in FY 91 for CDC participation in the PAHO-WHO project for global eradication of polio by 2000? Would this be a temporary or continuing appropriation?

Answer. The Pan American Health Organization (PAHO) has set a goal to eliminate polio from the Americans by the end of 1990 and the World Health Organization (WHO) has set a goal to eliminate polio from the world by the Year 2000. The United States could provide technical and laboratory resources. A total investment of $27 to $30 million over a ten year period would enchance this effort; however, CDC is not requesting additional funds for this purpose within the priorities of the 1991 budget, and no further offsets have been identified to accommodate such increases.

AIDS Education

Question. While the news about AZT and other AIDS drugs is encouraging, AIDS education remains the single best weapon we have in the fight against AIDS. However, despite Congressional direction to the states, many community-based education programs are not getting the funds they need to do their vital job. What is CDC doing to ensure that the States pass through at least 50 percent of their AIDS education dollars to organizations that can appropriately utilize them?

Answer. CDC Program guidelines require State and local health departments to plan and conduct HIV prevention programs in collaboration and coordination with AIDS service organizations, community organizations and other organizations/agencies that provide services to persons at risk. In fiscal year 1990, CDC initially awarded $60,144,202 to State and local health departments for HIV prevention, health education/risk reduction and minority initiatives. Nearly 500 non-profit community based organizations and local public agencies received an estimated total of $30,965,272, or 51.5 percent of the total funds awarded, to conduct HIV/AIDs prevention activities. When all funds are awarded, at least 50% will be awarded at the local level.

Question. Is CDC effectively monitoring and auditing the States to ensure Congressional intent is implemented?

Answer. CDC employs a number of mechanisms to ensure that Federal funds are expended in accordance with congressional intent and agency guidelines. CDC restricts funds and closely monitors State and local contracts with community and other local organizations to ensure that program funds are provided on a competitive and timely basis. CDC project officers maintain routine contact with State and local program personnel and conduct regularly scheduled site visits to observe program activities. In addition, CDC staff conduct comprehensive reviews of HIV prevention programs to learn in detail how well they have been implemented and to define problem areas. CDC staff then provide technical assistance to program personnel to resolve issues and problems identified through this process.

Fetal Alcohol Syndrome

Question. Does CDC have any ongoing efforts to educate pregnant women and practitioners of the dangers of fetal alcohol syndrome? If so, what is the cost of these efforts?

Answer. CDC has done studies which show that the Fetal Alcohol Syndrome (FAS) is not disappearing and that native American infants are 30 times and black infants 6 times as likely to have FAS as are white infants.

In order to provide a rational basis for CDC's work in the prevention of FAS, CDC contracted for a study to review the effectiveness of intervention methods. The draft report suggests that current data on effectiveness of intervention programs are not very encouraging. We do not know how to prevent this important cause of birth defects and developmental disabilities. Thus, CDC will initiate efforts to design and rigorously test intervention efforts to prevent FAS. In FY 1990, as the next step in this process, CDC will have this report peer-reviewed and will conduct a workshop to discuss a strategic plan to perform the intervention research needed to identify effective interventions. The draft report suggests that counseling of women who consume substantial amounts of alcohol during pregnancy may be an effective way of preventing FAS. The workshop will also make suggestions about how, with current knowledge, to conduct intervention programs among women who consume large amounts of alcohol. One objective of the workshop will be the development of guidance to State's and to CDC in this efforts to prevent FAS. In FY 1990, CDC estimates it will spend $100,000 on these activities related to fetal alcohol syndrome.

Question. I have heard from the state health departments and the American Academy of Pediatrics that pricing for public and private sector vaccines remains a problem. What are the current prices to the government for the major childhood vaccines -- OPV, DTP, and MMR?

Answer. The current Federal contract prices are:

Antigen	Price/dose	Contract expiration date
OPV	$1.92	1/28/91
DTP	7.961	5/13/90
MMR	14.713	2/26/91

Question. Please provide information on price increases in recent years.

Answer. Following is a summary of federal contract vaccine prices since 1977.

Selected Vaccines
Representative U.S. Price, 1977-February 1990
Price Per Dose

Year	DTP^{1}		OPV		MMR^{3}		Td (adult)^{4}		DT (pediatric)^{5}		HbPV		HbCV^{8}		IPV^{9}	
	CP	PC	CP	PC	CP	PC	CP	PC	CP	PC	CP	PC	CP	PC	CP	PC
77	$0.19	($0.15*)	$1.00	$0.295	$6.01	$2.42	$0.28	*	$0.28	*	NA	NA	NA	NA	-	*
78	0.22	(0.15*)	1.15	0.313	6.16	2.35	0.34	*	0.34	*	NA	NA	NA	NA	-	*
79	0.25	(0.15*)	1.27	0.332	6.81	2.62	0.47	*	0.41	*	NA	NA	NA	NA	-	*
80	0.30	(0.15*)	1.60	0.356	7.24	2.71	0.47	*	0.47	*	NA	NA	NA	NA	-	*
81	0.33	(0.15*)	2.10	0.396	9.32	3.12	0.52	*	0.52	*	NA	NA	NA	NA	-	*
82	0.37	(0.15*)	2.75	0.475	10.44	4.02	0.57	*	0.57	*	NA	NA	NA	NA	-	*
83	0.45	(0.42*)	3.56	0.582	11.30	4.70	0.62	*	0.66	*	NA	NA	NA	NA	-	*
84	0.99	(0.65*)	4.60	0.728^{2}	12.08	5.40	0.62	0.084	0.72	0.114	NA	NA	NA	NA	3.81	*
85	2.80	2.21	6.15	0.804^{2}	13.53	6.85	0.62	0.084	0.72	0.139	6.85	*	NA	NA	5.60	*
86	11.40	3.01	8.67	1.56^{2}	15.15	8.47	0.62	0.084	0.64	0.139	6.85	3.00^{6}	NA	NA	8.07	*
87	8.92	7.693	8.07	1.363^{2}	17.88	10.67	0.65	0.089	0.72	0.149	6.68	2.17^{7}	NA	NA	8.82	*
88	11.03	8.456**	8.07	1.363^{2}	24.11	16.18	0.78	0.158	0.78	0.191	7.55	1.56^{7}	13.75	11.00	13.79*	
89	10.65	7.961	9.45	1.92^{2}	24.11	16.18	0.64	0.1545	0.64	0.185	8.08	*	13.75	6.00	14.47	*
90	10.65	7.961	9.45	1.92^{2}	24.11	14.713	0.64	0.1545	0.64	0.185	-	-	13.75	6.00	14.47	*

CP - Catalog price of manufacturer who has the Federal contract for the year. PC - Federal Contract price. Federal contracts do not correspond to calendar or fiscal year time periods. NA - Vaccine not licensed

* - No Federal contract. These prices represent approximate cost on statewide contracts which were negotiated by individual State Health Departments.

** - Federal contract price was $9.623 per dose from January through May 13, 1988.

Prices from 1988 to the present include Federal Excise Taxes in the following amounts: DTP - $4.56 per dose; OPV and IPV - $0.29 per dose; MMR - $4.44 per dose; Td (Adult) and DT (Pediatric) $0.06 per dose

1. Cost per dose in 15 dose vials
2. Cost per dose in 50 x 1 Disposable pipettes
3. Cost per dose in 10 x 1 Dose packages
4. Cost per dose in 10 dose vials
5. Cost per dose in 10 dose vials
6. Cost per dose in 10 dose vials
7. Cost per dose in 5 x 1 dose vials
8. Cost per dose in 5 or 10 dose vials
9. Cost per dose in 5 dose vials

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

HIV PREVENTION AND SURVEILLANCE

Question. Does the President's budget for FY 1991 include funding to continue the CDC's Prevention and Surveillance Cooperative Agreements? If so, how much is assumed in the budget for these agreements? How does this compare with the amount available in FY 1990?

Answer. The FY 1991 President's budget does include funding to continue the CDC's Prevention and Surveillance Cooperative Agreements and the CDC will continue to provide direct funding to community based organizations and select cities. Thus far in FY 1990, CDC has awarded over $187 million. CDC expects the same level of funding in FY 1991.

Question. How does the CDC intend to maintain the existing direct cooperative agreements it now holds with localities and community based organizations?

Answer. The CDC will support the existing cooperative agreements by providing funds directly to the community based organizations and select cities.

QUESTIONS SUBMITTED BY SENATOR TED STEVENS

Vital Statistics Cooperative Program

Question. Does the President's budget request include full funding for all components of the Vital Statistics Cooperative Program, including the new linked infant death and birth project?

Answer. The President's budget contains funds to fully fund all components of the vital statistics system including birth, death, fetal death, marriage and divorce, induced termination of pregnancy, and the program to link birth and infant death records.

Hepatitis B in Alaska Natives

Question. Hepatitis B is a major health problem in Alaska Natives. What is the status of the hepatitis B program in Alaska and what more needs to be done to control hepatitis B in Alaska?

Answer. In 1984-85, the Alaska Department of Health conducted mass hepatitis B serologic screening for the general population (including Alaska Natives) and offered vaccine to those who were seronegative. The State Health Department now provides serologic screening and hepatitis B vaccine to non-native indigents at high risk of exposure to hepatitis B.

In 1983-85, the Indian Health Service conducted mass hepatitis B serologic screening of all interested Alaska Natives and offered vaccine to those who were seronegative. Presently, on request, any Alaska Native, regardless of age or potential risk will be serologically screened for hepatitis B. Seronegatives are offered hepatitis B vaccine. During routine or acute care visits, those who have begun, but not completed, their vaccine series are offered the additional doses needed for completion. Special efforts will be undertaken in 1990 to identify all children, adolescents, and young adults through 18 years of age who have not been screened and/or completed their vaccines so they can receive these services.

All pregnant Alaska Natives are now screened for hepatitis B during the first prenatal visit. Infants born to seropositives receive HBIG and the first dose of hepatitis B vaccine prior to hospital discharge. Vaccine doses 2 and 3 are administered during routine pediatric visits at six months and one year. Infants born to seronegative mothers receive the 3-dose hepatitis B vaccine series at birth, two month, and three months. In the Bethel area, all seronegative pregnant women are given vaccine postpartum. Additional efforts by the Indian Health Service could include the immunization of school-aged children and the more vigorous pursuit of adults who have not been screened, as well as, those who have begun, but not completed their vaccination series.

Injury Prevention and Control in Rural Settings

Question. Given those factors unique to Alaska, such as the nature of rural areas, climate, occupational specialties, and Alaskan Native population, how is CDC defining the extent of the injury problem and addressing the prevention and control of injuries in these settings?

Answer. The extremes of Alaska's environment and geography post challenges to the design and planning of its injury control programs. Recognizing these challenges, CDC has provided funding for the State health department to conduct a model surveillance program designed to determine the dimensions of head and spinal cord injury. Earlier studies, which CDC conducted cooperatively with the Alaska Department of Health, identified at least five different sources for information about injuries in the State, ranging from death certificates and hospital records to newspaper clipping sources. The model surveillance grant program will use these sources and explore new data sources to identify traumatic brain and spinal cord injuries. This injury surveillance project, one of seven three-year programs CDC funds nationally, will serve as a means to identify potential risk factors for injuries and will lead to development of localized and targeted prevention programs.

In September 1989, the Centers for Disease Control awarded the State of Alaska a Injury Capacity-Building grant to facilitate the development, expansion, and improvement of the State's injury control initiative. This funding is to establish or strengthen the Department of Health as the lead organization for the prevention and control of injuries in Alaska. This funding provides a further opportunity to define and track the injury problem, develop community interventions which focus on priority injuries, mobilize broad collaborations for intervention and public education, and evaluate the program's overall effectiveness in terms of reduced morbidity, mortality, severity, disability, and cost. This is one of 15 awarded in FY '89 to State and local public health agencies for a four year period.

Childhood Injuries

Question. I have had a long-term interest in childhood injuries. Would you please outline the major injuries that affect children in our country, and describe briefly some activities CDC is carrying out to address this problem?

Answer. Last fall we completed a comprehensive review of the childhood injury problem in a report to Congress. The report to Congress on childhood injuries pointed out that among children, 47% of injury deaths in 1986 were due to motor vehicle related injuries, 13% of childhood deaths are attributable to homicide-the second leading cause of injury death among children, fires and burns are the sixth major cause of injury death among persons below age 19-accounting for 7% of deaths, and almost 30% of childhood injury deaths result from head injury. The CDC Injury Control Program carries out a number of activities that address the problems described in the report including:

- Among extramural grants funded by CDC is a project in Kansas City to identify high-risk youth and adults who have been involved in violent disputes and provide them with conflict resolution skills training, and a cohort study in Houston and Baltimore examining battering of pregnant women.

- A descriptive evaluation of the increase in the numbers of youth homicides in Los Angeles is examining the higher rates found for Hispanics and blacks. At the request of the Los Angeles County Department of Health Services and the Los Angeles Police Department, an analyses of various data sources with emphasis on gang involved youth homicides is being carried out. The purpose of the study is to identify trends, high-risk groups, and potential risk factors for youth and gang homicides in Los Angeles.

- Funded a major grant with the Michigan Department of Health to implement a bicycle helmet campaign to identify effective components of a program to prevent head injuries occurring while riding a bicycle.

- Analyzed and published a journal article on all head injury deaths in the U.S. to identify high risk activities and age, race, and sex groups.

- In FY 1989 fifteen Injury Capacity Building grants were awarded by CDC to State and local public health agencies. Among the activities the grantees are undertaking as they develop comprehensive, coordinated injury control programs, are elements addressing childhood injuries. Some examples are:

  - Oklahoma's Child Homicide Study will form the basis for establishing intentional injury intervention programs.

  - New York City has begun focusing on gunshot wounds in children under 14 as they develop urban models for injury control

- Colorado is promoting occupant protection for children under 15.

- Missouri is expanding and evaluating a child injury fatality surveillance system.

- The entire initial thrust of Minnesota's grant activities is a coordinated approach to childhood injuries. This will allow community needs assessments, statewide surveillance, and programs in safe home awareness and positive parenting.

- Washington will implement 8 child injury preventions projects in local health departments.

- San Antonio will develop a 24-hour telephone hotline for poison control, with bilingual and deaf capabilities.

In addition, we have undertaken an evaluation project with another part of CDC to assess the effect of State regulations and enforcement relating to childhood injuries at day care centers. This initiative was partially based on our study of injuries occurring at Atlanta day care centers which found the playground to be the site of most of the severest injuries.

Suicide

Question. One of the greatest impacts of injury in Alaska is suicide. What is being done to address this problem?

Answer. The report of the Secretary's Task Force on Youth Suicide contains recommendations on data development, evaluation research, service delivery, and education. CDC's Injury Control Program is conducting several activities that address these recommendations. They include supporting injury surveillance projects which cover suicide and suicide attempts, developing a prototype suicide attempt surveillance system in Cobb County, Georgia; and participating with the New Jersey Department of Health in conducting a workshop to develop "CDC Recommendations for a Community Plan for Prevention and Containment of Suicide Clusters", and initiating a project entitled "Youth Suicide Evaluation: Program Descriptions, Evaluation Status, and Barriers to Implementation."

Infant Mortality Rates

Question. Certain of our Alaskan population, especially Alaska Natives, have high infant mortality rates. What is CDC doing to address this issue?

Answer. The Centers for Disease Control has estimated that at least 30% of infant deaths could be prevented if this nation were to implement what we know will work. The failure to meet the 1990 Prevention Objectives for Infant Mortality and to reduce the unacceptable gap between black and white infants' survival was due in part to the States' lack of sufficient data and statistical and epidemiological capacity to target existing resources, to develop new interventions, and to monitor program impact. At present, State maternal and child health (MCH) programs have little access to surveillance expertise and analytic capability--areas of CDC leadership. Existing surveillance activities in States are incomplete and do not permit State-to-State comparisons, adequate linkage to national surveillance efforts, or appropriate monitoring of quality control issues.

To help States better address this health issue, CDC has developed and initiated a comprehensive mechanism to:

- Identify those populations at highest risk.
- Enable States to target their intervention efforts.
- Provide resources for evaluating progress toward the Year 2000 objectives related to maternal and infant health.

In 1991, CDC will be devoting $26.1 million specifically on non-AIDS projects related to reducing infant mortality. THis is an increase of $11.5 million over 1990. Infant mortality prevention activities at CDC are an integrated effort including surveillance, epidemiologic studies, technical assistance to State health agency personnel, and limited direct research targeted to the reduction of perinatal, neonatal, and postneonatal mortality and morbidity related to low birth weight, sudden infant death syndrome (SIDS), fetal alcohol syndrome (FAS), congenital anomalies, prematurity, complications of pregnancy, and major nutrition-related health problems in infants and pregnant women.

In this partnership with States, efforts are directed toward reducing adverse pregnancy outcomes in defined high-risk groups (Blacks, Native Americans, etc.) by identifying behavioral risk factors (e.g., smoking, alcohol use, etc.) and developing and evaluating relevant interventions.

Specific to Alaska, since June 1989, the CDC has provided technical assistance to implement the Preganancy Risk Assessment Monitoring System (PRAMS), through which population-based data are collected about maternal behaviors that occur during pregnancy and the child's early infancy. Each month a sample of new mothers are selected from birth certificates. To be sure that adequate data are collected for Alaskan Natives, this group is over-sampled. Mothers are contacted 3-6 months after delivery and asked to complete a questionnaire. Questionnaire data are linked with infant birth certificates. When sufficient data are collected, the CDC will assist staff from Alaska's Division of Public Health in using PRAMS data to identify needs, assess problems, target programs, and evaluate interventions.

Currently six States and the District of Columbia participate in PRAMS. Because 75% of the questionnaire is the same for all States, PRAMS data also are useful for comparing the prevalences of maternal behaviors between States. In addition, PRAMS data can be used by States to monitor their progress toward the YEAR 2000 Health Objectives and to meet Title V reporting requirements.

HIV and STD Prevention

Question. What activities of the CDC, Division of STD/HIV Prevention (DSTD/HIVP), target Alaska Native populations for HIV and STD prevention?

Answer. CDC, DSTD/HIVP supports a number of specific programs and special projects in Alaska which directly target Alaska Natives for both STD and HIV prevention:

- A demonstration chlamydia control/STD prevention project has been developed for the Kotzebue Region to serve as a model program for other areas. The pilot phase of this project is currently underway and includes a regional measure of STD prevalence (including gonorrhea, chlamydia, and human papillomavirus), as well as, other preventive activities including Papanicolaou screening and cervicography. This project will measure the incidence and prevalence of STD over time following STD control interventions including widespread screening and partner notification.
- A demonstration chlamydia control project in Region X-Family Planning Programs has included screening and treatment for women in the Bethel area when they present for family planning services.
- CDC provides National and Regional Minority Organizations Grant Program funds directly to the Alaska Native Health Board for HIV prevention activities. This program targets Alaska Natives throughout the State.
- For the past two years CDC has provided funding to the Indian Health Service (IHS) through a Memorandum of Agreement (MOA) for HIV prevention efforts. This agreement will continue in fiscal year 1990, and includes funds to support HIV prevention activities in Alaska. In addition, CDC is developing a MOA with IHS to support STD prevention activities conducted by local service units in selected IHS Service Areas.
- Through separate cooperative agreements for STD and HIV Prevention, the State of Alaska receives funding from CDC for HIV prevention efforts (including counseling and testing activities) as well as for STD prevention activities (including surveillance) which will affect Alaska Natives in both rural and urban areas.

HIV Infection

Question. Are Alaska Natives at high risk for contracting HIV infection/AIDS?

Answer Individuals of American Indian and Alaska Native (AI/AN) race residing in Alaska are at risk for human immunodeficiency virus (HIV-1) infection and AIDS, particularly if they share needles or have sex with an infected person.

To date (May 1, 1985 - December 31, 1989), of the 2,873 HIV tests performed on Alaska AI/ANs through the Alaska State Counseling and Testing System, 21 (0.7%) were positive for HIV-1 antibodies. This compares to 282 (1.8%) of the 15,560 tests on individuals of all other racial groups combined during the same interval in the same system.

As of December 31, 1989, 8 (or 10.3/100,000 population) Alaska AI/ANs had been reported to the Alaska State Health Department as persons having AIDS. This compares to 72 (15.7/100,000) for all other races combined in Alaska. However, preliminary data from the Seattle, Washington area indicate that the true number of AI/AN AIDS cases in the Seattle area may twice that which had been previously reported, due to racial misclassification of AI/AN AIDS cases by reporting entities in the Seattle area. The potential for this type of racial misclassification in Alaska has yet to be determined. Another indication that AI/ANs are at risk of HIV infection is the sexually transmitted disease (STD) rates which are very high for Alaska Natives. For the period 1984-1988, gonnorhea rates were 1,470/100,000/year for AI/ANs in Alaska, versus 284/100,000/year for Alaskans of all other races; and syphilis rates were 1.8/100,000/year for AI/ANs, versus 1.1/100,000/year for Alaskans of all other races. The same behaviors which place individuals at risk for STDs place them at risk for HIV infection and AIDS.

The Centers for Disease Control is currently assisting the Indian Health Service (IHS) in conducting a blinded HIV-1 seroprevalence study of prenatal, STD, and drug and alcohol patients seen in facilities funded and operated by IHS throughout Alaska. Preliminary results of this study should be available in late 1990. This study will provide more accurate estimates of HIV-1 prevalence among Alaska Natives, and permit follow-up over time.

HIV Funding

Question. If AIDS prevention funds were provided by formula as authorized by the Health Omnibus Programs Extension Act of 1988 instead of the current award method, how would funding for the State of Alaska, Hawaii, and Maine be affected?

Answer. If HIV prevention and education funds (Health Education and RIsk Reducation, Minority Initiative, Public Information) had been allocated by formula in fiscal year 1989, as authorized by the Health Omnibus Programs Extension Act of 1988, Alaska, Hawaii, and Maine would have been awarded lesser amounts. The following is a comparison of the actual awards to what would have been awarded if the formula had been utilized.

STATE	ACTUAL FISCAL YEAR 1989 AWARD	HYPOTHETICAL FORMULA AWARD
Alaska	$ 503,840	$ 100,000
Hawaii	$ 551,083	$ 170,898
Maine	$ 249,092	$ 134,247

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

DRUG BUDGET

Question. Dr. Goodwin, you have proposed to increase the block grant by $100 million, or 7.7 percent, and the Office for Substance Abuse Prevention by $69 million, or 36 percent. The one good thing about the block grant is that it goes out by a formula and all States share in the program.

Why are you proposing to increase the Office for Substance Abuse Prevention at a rate almost 5 times greater than the block grant?

Answer. From FY 1988 to FY 1990, State funding for treatment and rehabilitative services under the block grant has grown from $643 million to $1.2 billion, a $550 million increase. During this same time, we have established a national drug abuse prevention program designed to address the source of the substance abuse problem. This has resulted in the formation of OSAP whose FY 1991 request of $262 million is less than one-fourth of the national treatment effort. While the creation of this new drug abuse prevention program has resulted in some large percentage increases over the relatively little prevention done previously, these increases are relatively modest in context of the Department's drug budget, and given its change.

Specifically, the $69 million increase in FY 1991 reflects program enhancement for three of the six OSAP demonstration programs: $50.0 million to maintain the same level of new grants for the high priority Community Partnership Program. This program is similar to the "Fighting Back" program sponsored by the Robert Wood Johnson Foundation. The High Risk Youth program increases $5.7 million and the Pregnant Women and Infant program by $5.2 million. Each received $3.9 million for new grants; overall, each program has increased in FY 1991 by 15 percent over FY 1990.

SUBSTANCE ABUSE IN IOWA

Question. Estimates of substance abuse problems in my home State of Iowa indicated that at least 180,000 Iowans are substance abusers, and that between 26,000 and 27,000 young Iowans need some form of substance abuse treatment. The economic impact of substance abuse in Iowa is over $700 million a year in lost productivity, medical costs, crime and destruction of property, and other social costs. This problem is definitely not just focused on urban areas and urban States like New York and California.

What are you doing to insure that rural States and smaller cities are not last in the distribution of funds?

Answer. In FY 1990, the Office for Treatment Improvement (OTI) will announce a grant demonstration program to assist States and communities in enhancing existing drug abuse treatment programs for specific population subgroups that are facing such critical health and socio-economic difficulties as a result of their drug abuse as to characterize them as critical populations. This new grant program will focus on the critical populations of adolescents, racial and ethnic minority populations, and residents of public housing projects. OTI is particularly interested in funding projects that address the population subgroups of drug abusers who are homeless, have a co-occurrence of drug addiction and other health disorders, or are in a rural area.

The award criteria for grants under the Critical Population announcement described above will be based on the application's technical merit and its focus on the program's target populations and subgroups. OTI will further consider the balance among target populations and the geographic distribution of grants in making awards. In this way, OTI will ensure an equitable distribution of funds to rural areas.

All of the OSAP demonstration grant programs have, as an award criteria, geographic balance. This is intended to ensure as equitable a distribution of funds as possible in order to meet the needs of urban as well as rural areas.

In addition, support is provided to all States in the form of the ADMS Block Grant. Block Grant funding for Iowa has increased from $4.8 million in FY 1989 to $7.8 million in FY 1990. The President's FY 1991 Budget requests $8.4 million for Iowa.

Question. Should we target programs in the Office of Substance Abuse Prevention and the Office of Treatment Improvement to smaller towns and communities in rural States?

Answer. Yes, two programs specifically target these areas. The Critical Population grant demonstration program in OTI targets rural areas, particularly those where 1) demand for drug treatment exceeds capacity, 2) there is a high prevalence of drug abuse, and 3) there is a high incidence of drug related criminal activities. The smaller towns and communities in rural States that face these problems will be served by this demonstration program when they are included as sub-recipients in the application from the State.

During FY 1990 OSAP initiated the Community Partnership Demonstration Program, designed to promote the development of long-range, comprehensive, community-wide substance abuse prevention programs through the formation of public and private sector coalitions. Under this program grant applications are solicited from communities, which are stratified into three categories, by population and relative rural/urban character. Included within these three categories are small communities and/or rural areas. This stratification helps to ensure that rural communities and small cities will receive a fair share of funds.

SUBSTANCE ABUSE AMONG WOMEN AND CHILDREN

Question. In my home State of Iowa, it is estimated that 2,000 "cocaine babies" will be born this year. Your budget estimates that as many as 375,000 infants or 11 percent of the babies born in this country, are affected by maternal substance abuse. Your budget justification also notes the great difficulty many of these women encounter in trying to get treatment.

Yet the FY 1991 budget proposes less than $4 million in new funds, for just 15 new grants for substance abusing pregnant women and their infants.

What are the current estimates of women and infants needing treatment and the number of treatment slots available?

Answer. There is no currently available, reliable, agreed upon measure of the number of women and infants needing drug abuse treatment. Some estimates of the general magnitude of the problem can be made however. Based on the 1988 Household Survey, it is estimated that 2.5 million women used illicit drugs 50 or more times in the past year. More than half of these, 1.3 million, used 200 or more times in the past year. It is likely that a sizable proportion of this group do or will need some form of treatment.

The first national hospital incidence survey conducted by the National Association for Perinatal Addiction Research and Education (NAPARE), estimates that as many as 375,000 infants may be affected each year. It must, however, be cautioned that this estimate is based on a small pilot study of 36 mainly urban hospitals where illicit drug use by pregnant women ranged from a low of 0.4 percent to a high of 27 percent. The drugs used by these pregnant women included cocaine, marijuana, amphetamine, as well as others. No accurate data were available on the amount, frequency, and methods of use of any one particular drug, nor the relationship of drug use to time of pregnancy.

ADAMHA will increase spending for pregnant and post-partum women from $101,505,000 in FY 1990 to $110,392,000 in FY 1991. These amounts exclude the 10 percent set-aside for women in the ADMS Block Grant. ADAMHA's program includes:

> NIDA research on the effects of maternal drug abuse on infant development and research demonstrations to develop new therapeutic approaches or correct deficiencies in existing clinical programs designed to treat drug abusing women of child bearing age as well as pregnant, post-partum women and their infants.
>
> OSAP supports programs which are community-based models of education, prevention, and/or treatment for substance abusing women and their infants. These demonstration grant programs are designed to promote the coordinated participation of multiple organizations in the delivery of comprehensive services for these women.

ADAMHA estimates that in FY 1991, $538 million will be available to fund 107,746 treatment slots for all groups of drug abusers. This is an increase of $29 million and 4021 slots over FY 1990. Programs that fund capacity expansion are the ADMS Block Grant, OTI's Treatment Grants in Crisis Areas and Treatment Improvement Grants, and some of NIDA's Demonstration programs. Federally funded slots are a small portion of the treatment slots available to groups including pregnant and post-partum women. Estimates of non-federal treatment capacity range from a low of 276,255 slots to a high of 561,255 slots in FY 1991.

Based on the 1987 National Drug and Alcohol Treatment Unit Survey (NDATUS), there were 6,558 treatment units in the United States that provided drug abuse services. Of these, 5,015 reported their treatment capacity, which totaled 328,838 slots. While most units may treat women, 1,547 of them reported that they had special programs for women. These units reported a capacity of 108,606 slots.

Since no accurate estimates of drug-exposed infants are available at this time, it is equally difficult to estimate the number of infants needing any type of treatment. NIDA, however, will fund a major study to determine the prevalence of drug use among pregnant women that will provide estimates of pregnant women using illicit drugs during pregnancy and the number of drug exposed infants born to them.

Question. How many applications have been received for the Pregnant Women and Infants demonstration program so far, and is the Office for Substance Abuse Prevention going to run a new grant cycle this year?

Answer. During FY 1989, when the Pregnant and Post Partum Women and their Infants Demonstration Program was initiated, the Office for Substance Abuse Prevention had one review cycle in May. For that cycle, a total of 135 applications were received.

During FY 1990, the Office for Substance Abuse Prevention will have two review cycles: November 1989 and April 1990. For the November 1989 review cycle, 182 applications for this program were received.

Question. How many applications have been approved for funding under the Pregnant and Post Partum Women and their Infants Demonstration Program so far, and how many actually have received funding?

Answer. From the May 15, 1989 review cycle, 72 applications for the Pregnant Women and Infants program were approved for funding. Of these, 45 grants were awarded.

EDUCATION EFFORTS

Question. When discussing effective substance prevention programs, your budget justification notes that "almost every successful program involves the school system." (p. 169)

I was surprised to hear Drug Czar William Bennett say last week that he thinks education is not key to solving the nations drug abuse problems. Dr. Bennett says children respond to tough policy and punishment not education.

--Who's right--Do you think prevention and education efforts are useful in the drug wars?

Answer. Prevention and education efforts are an essential and productive component of the war on drugs. While many school-based informational and educational efforts have been implemented and evaluated, strictly scientific evidence that these types of programs have substantial effects on substance abuse is difficult to obtain. But this is difficult for many social issues, including incarceration. Eradication or interdiction can help stem the supply: treatment programs can deal with those already afflicted. Only prevention and education efforts will make a long term difference.

SUBSTANCE ABUSE DEMONSTRATIONS

Question. The Office for Substance Abuse Prevention is directing several programs to enhance treatment capacity for target groups such as pregnant addicts and high risk youth, and to help communities develop prevention strategies to fight drug and alcohol abuse. The budget request would increase spending for OSAP demonstration projects from $155 million to $220 million. How many projects would this budget support in FY 1991 compared to FY 1990, and about how many individuals would be served?

Answer. The FY 1991 budget request will provide an additional $65 million over the FY 1990 appropriation. Of this amount, $7.5 million provides an inflationary increase for all the OSAP programs. The remaining $58.7 million in new funds is distributed as follows: $50.0 million for the Community Partnership Program; $3.9 million for High Risk Youth; and $3.9 million for the Pregnant Women and Infant program.

The FY 1991 level will support approximately 783 new and continuing projects compared to 596 projects in FY 1990.

Given the number of youth and families estimated to be served under the demonstration grant programs as well as the over 315 communities and its members to be served under the Community Partnership program, OSAP roughly estimates that it will reach over 58 million individuals during FY 1991.

Question. Do you intend to reserve any of the FY 1991 new funds for second tier cities and rural States?

Answer. In FY 1991, $50.0 million in new funding is provided for the Community Partnership Demonstration Program. Under this program, funds are provided to communities of specified population size and rural/urban character, to support the development of long-range, comprehensive, community-wide substance abuse prevention programs. This stratification will help ensure that rural communities and small cities will receive a fair share of funds.

EFFECTIVENESS EVALUATIONS

Question. What progress can you report on research to learn more about the effectiveness of various modalities for treating drug abuse, particularly cocaine and "crack" and "crank"?

Answer. NIDA can report considerable progress in learning more about the effectiveness of various modalities for treatment of drug abusers. For example, research from treatment outcome studies has shown that drug abuse treatment does reduce illicit drug use and criminal behavior as well as improving social and occupational functioning. It has also demonstrated that the rate of seropositivity for HIV infection among IV drug abusers is lower for those in methadone treatment. Studies of methadone treatment have shown that program leadership, staff morale, staff stability, variety of services, and adequate methadone dose levels are important factors in program success.

Research on the development of new medications for use in the treatment of drug abuse is currently focusing on a number of drugs which show promise. These include clonodine, LAAM and buprenorphine for the treatment of narcotic addiction Desipramine, Flupenthixol, Carbamazapine, Verapamil, Diltiazem, and Bromocriptine for the treatment of cocaine addiction.

Studies of non-pharmacological treatment techniques have shown that certain methadone patients show greater improvement with behavioral or psychoanalytically oriented psychotherapy in addition to drug counseling; that the characteristics of drug abuse counselors and psychotherapists are correlated to outcomes in the treatment of opiate abusers; and that there is a correlation between the severity of psychiatric disorders and drug abuse treatment outcome.

Question. Do you see a time soon when ADAMHA will be able to recommend a treatment modality or setting for cocaine abuse treatment with any measure of confidence in its success?

Answer. NIDA is investigating numerous potential interventions which may offer some degree of success in treating cocaine abusers. We are hopeful that some of these approaches will form the basis of a modality/modalities which can be recommended for cocaine treatment, but systematically testing these approaches will take several years. Where heroin addiction is concerned, we have a variety of pharmacological interventions available, with the prime examples being methadone (agonist treatment) and naltrexone (antagonist treatment). Where cocaine is concerned, no such presently available pharmacotherapy has been developed, although NIDA is currently investigating nearly twenty medications which are thought to have potential as the basis of new treatment modalities. Among the pharmacologic strategies being investigated are medications which may block the euphoric effects of cocaine, prevent craving, not cross the placental barrier, and prevent or ameliorate cocaine toxicity.

The more generic nonpharmacological treatments which have been found to be useful in treating cocaine abusers include behavior therapies (e.g., contingency management) in outpatient settings, relapse prevention training, and therapeutic community treatment, and self-help groups such as narcotics anonymous. Potential treatments under development include a technique which involves exposing the drug abuser to something that reminds him/her of and stimulates a craving in him/her for the abused drug (i.e., the stimulus), without providing him/her with the pleasurable reinforcement of the drug. This stimulus is repeated until the drug abuser no longer experiences a craving for the drug, i.e., the craving is "extinguished." Extinction has shown some success in reducing conditioned withdrawal and craving in the laboratory setting, but its success outside the laboratory has yet to be established. At present, it is viewed as a useful addition to, but not substitute for, the appropriate use of psychotherapy and drug abuse counseling.

Aversive conditioning techniques for the treatment of drug abuse are in the preliminary stages of development. These involve pairing a stimulus for the drug of abuse with an aversive stimulus (e.g., inducing nausea in a patient who is thinking about using cocaine), so that the drug abuser learns to associate drug abuse with negative consequences.

Social skills training has been shown to be helpful in the treatment of alcohol abuse, but its efficacy in the treatment of other forms of substance abuse has yet to be demonstrated. Projects are currently being carried out that examine the usefulness of social skills training in the treatment of substance abuse. Other forms of skills training, such as job-seeking skills training, have been shown to be of some value when used with drug abusers.

Question. Are there any longitudinal research projects underway in ADAMHA to study drug abuse prevention approaches?

Answer. NIDA is currently funding three longitudinal research projects to study the impact of prevention interventions.

Dr. Mary Ann Pentz, at the University of Southern California is conducting a comprehensive community drug abuse prevention program in Kansas that includes five strategies: mass media, school-based peer counseling/resistance skills training program, parent education and organization, community organization, and health-related policies that have anti-drug components. All middle and junior high schools and communities in Kansas City are included in this study. During the first year, the project introduced a school-based peer resistance program called STAR (students taught awareness and resistance) which consists of classroom and homework sessions focused upon the psychosocial consequences of drug abuse; correction of attitudes concerning the prevalence of drug use; social resistance training to offset and counter influences to use drugs; assertiveness and problem solving training; and, a statement of public commitment to avoid using drugs. The remaining interventions include: parent/family drug education and community organization activities through creation of a drug council or task force, and efforts to change health-related policies in the community. Results from the first year indicate that sixth and seventh grade students in the program report significantly lower levels of alcohol, cigarettes, and marijuana at one year follow-up than students in the control group. Preliminary research indicates that these initial differences are maintained over the following four years.

Dr. J. David Hawkins, at the University of Washington is conducting a multi-strategy school-based intervention testing the efficacy of a comprehensive family, school, and peer focused prevention program with students in grades 4-6. The experimental program is designed to promote social bonding and to enhance effective learning, cooperation among peers, and positive attitudes toward school. Children were also taught peer refusal skills to resist social pressure to use drugs. Parents were trained to increase their children's involvement in the family through productive roles and activities, clarify and communicate family expectations about drug use by family members, and teach their children to resist peer pressure to use drugs. Preliminary results indicate positive outcomes for experimental students on five factors: reductions of antisocial behavior, improved academic skills, increased commitment to school, reduced levels of alienation and poor bonding to others, and reduced school misbehavior. In addition, a reduction of drug use at school was also reported.

Drs. James Anthony and Sheppard Kellam at Johns Hopkins University are conducting a joint effort between the Prevention Research Center of Johns Hopkins University and the Baltimore City public schools. Based on the work of Dr. Kellam in Chicago among elementary school children, this program is designed to address factors associated with later development of drug abuse: aggressiveness and antisocial behavior; shyness; and reading difficulties in first through third grade. The current research is designed to provide interventions to address these three factors directly. Teachers in grades one and two of the Baltimore City public schools have received special training to conduct the interventions of mastery learning and good behavior games. Early results indicate increases in reading and math levels and improved school behaviors.

MENTAL HEALTH BUDGET

Question. Overall, the FY 1991 budget requests an 18 percent increase in drug abuse research, a 5 percent increase in alcohol research, and about a 6 percent increase in funds for mental health research.

For non-AIDS research, however, the budget request allows for a 13 percent increase in drug abuse, and less than a 5 percent increase in alcohol and mental health research.

While the block grant goes up $100 million, all of the increase is reserved for drug abuse.

In view of the documented need for expansion in mental health treatment and research, does this budget shortchange mental health and mental illness priorities?

Answer. Recent priorities including the "War on Drugs" dictate large increases in drug abuse programs. This, however, does not shortchange mental health or mental illness priorities.

The FY 1991 budget for mental health research includes $481.9 million for the full range of NIMH research activities. These funds will support 1,145 research project grants and 45 research centers, including one new molecular neurobiology center. The Institute's high priority on research training is reflected in an increase of 31 trainees over the FY 1990 number.

In FY 1991, $26.9 million is provided for both the adult and child demonstration programs, including $4.0 million to continue funding of 20 prevention services research demonstration projects to assist in the care of persons who are mentally ill.

This budget provides sufficient funds for the necessary expansion within NIMH including the funding for a new program office for Rural Mental Health and new initiatives associated with the "Decade of the Brain." NIMH also benefits from basic research conducted by the National Institute for Drug Abuse such as comorbidity research which has potential mental health implications.

EFFICACY OF CURRENT BLOCK GRANT MECHANISM

Question. One of the problems associated with having just one block grant to deal with treatment of substance abuse and mental health disorders is that it's difficult to increase funds for just one or the other.

Mental health advocates have complained that even though ADMS funds have just about doubled in the last two years, they haven't benefitted. And I know the Administration was frustrated last year in its attempts to increase funding only for drug abuse.

Dr. Goodwin, do you think the single ADMS Block Grant we have now is the most effective way to direct funds to States, or should we be looking at another method, such as separate block grants for substance abuse and mental health?

Answer. ADAMHA does not object to two formulas for determining the substance abuse versus mental health portion of a State allotment. We do feel strongly that the State should be able to apply using one application; ADAMHA should be able to make one grant award covering both allotments. The amount designated for each of the two programs would be identified in the grant award statement.

Beyond the obvious administrative and staff savings from having to submit a single application, there are many programmatic reasons for not having separate block grants for substance abuse and mental health. The most compelling of these reasons is the need of individuals receiving the services funded by ADMS Block Grant funds. Service providers at the State and local levels continue to recognize that their clients require multiple services. Individuals with mental health problems often also require help for substance abuse problems and vice versa. The funding source is often a major factor in determining if dually-diagnosed clients receive fully integrated ADM services or separate, fragmented, and uncoordinated treatment at the State level.

Most States, recognizing the needs of their clients, have adopted a coordinated planning approach to ADM service delivery. They combine mental health and substance abuse needs in their planning process to ensure integration of service delivery and to avoid duplication of effort. A single funding source contributes to the success of coordinated planning efforts in a variety of ways. For example, it provides States the capacity to shift up to ten percent of their funds between substance abuse and mental health as needed.

State organizational structure also supports the continuation of a single combined block grant. A dozen States are organized with the mental health component having authority over substance abuse. Most of the other States, recognizing the need for coordinated services, give mental health and substance abuse equal organizational weight and frequently combine them under a single authority. Once again, a single funding source supports this kind of organizational decision.

CHILDREN'S MENTAL HEALTH

Question. The National Mental Health Advisory Council has recommended $60 million for the new child research plan. Why isn't this reflected in the Administrations's budget?

Answer. The National Mental Health Advisory Council report was not available at the time the Administration's budget was submitted but its recommendations would have been considered among competing demands on resources such as the "War on Drugs" and Head Start. The FY 1991 budget request does reflect many of the priorities outlined in this report.

The President's Budget includes $111.9 million to support a wide range of research on this growing national concern. The report is currently being reviewed and will receive full consideration in the formulation of the FY 1992 budget.

STATE COMPREHENSIVE MENTAL HEALTH PLANS

Question. P.L. 99-660 requires States to prepare and implement comprehensive plans to shift mental health services from an institutional to a community-based setting. It also requires HHS to assess whether States are implementing the plans required under that law. If a State hasn't "fully implemented" its plan by September 30, 1991, its allocation under the ADMS block grant is to be reduced.

ADAMHA has not allocated funding or staff to conduct State assessments in FY 1990.

How will ADAMHA meet its obligations in FY 1991 to assess whether States are complying with the law?

Answer. The P.L. 99-660 program is administered under the State Mental Health Planning Program which is part of the Mental Health Services Development Branch of the Division of Education and Service Systems Liaison, NIMH. While it is true no additional staff or funding has been allocated by ADAMHA to conduct State assessments in FY 1990, the staff that has had programmatic responsibility for carrying out ADAMHA's responsibilities under P.L. 99-660 remains in place and continues to carry out P.L. 99-660 activity. This staff is presently in the process of developing a reporting format for States to report on how they have "substantially implemented" their P.L. 99-660 plan. This report is due September 30, 1990. This reporting format will also be used as a basis for the "fully implemented" requirement of September 30, 1991. These reports on implementation follow the previous submission of State plans which took place on September 30, 1989. It should be noted that ADMS Block Grant reductions may be tied to a determination of "non compliance" based on a review of State materials submitted on any of the above dates.

AIDS MENTAL HEALTH RESEARCH DEMONSTRATION

Question. There is an AIDS mental health research demonstration project authorized by P. L. 100-607, which would demonstrate effectiveness methods of providing mental health services to people who have experienced severe adverse reactions to an HIV test.

Your budget justification mentions collaboration between NIMH and HRSA on this demonstration program, yet the HRSA budget justification doesn't mention the program at all. Moreover, there are no actual funds provided for the conduct of this program within the PHS at all.

What has NIMH done to implement this program in FY 1990, and what is planned for the program in FY 1991?

Answer. In response to the HOPE legislation, NIMH and HRSA are working together in FY 1990 to evaluate existing HRSA programs which include a mental health counseling component. In FY 1989, NIMH developed an HIV-related counseling strategy following a meeting of research and clinical experts in HIV mental health counseling. Currently, NIMH and HRSA are developing a process to assess the mental health counseling components of HRSA AIDS Service Demonstration Programs. This is consistent with the provision in the counseling strategy that counseling and mental health services for HIV-infected individuals (and their friends and others) would be most appropriately provided within an ongoing health service program. An assessment of existing counseling approaches appears to be a reasonable strategy to review the state of knowledge regarding effective mental health counseling and gaps in mental health treatment related to HIV infection and AIDS.

The need to provide mental health counseling within a program of integrated biopsychosocial care to the growing number of HIV-infected individuals, their families, caregivers, and significant others, is increasing. Learning of a positive test result may have profound psychological effects on the individual, such as social isolation, paralyzing anxiety, depression, and even suicide.

From a primary disease prevention perspective, the behaviors that transmit HIV infection are modifiable. Counseling of HIV-positive individuals is one strategy to produce behavior change that will reduce the further spread of HIV. Effective prevention strategies require the cooperation and support of infected persons and their integration into adaptive social support networks, factors which are adversely affected by psychological distress and poor mental health functioning.

NIMH continues to place a priority on research to develop, implement, and evaluate pre- and post-HIV antibody test counseling and ongoing mental health counseling designed to prevent both severe psychological consequences and behaviors that will further transmit HIV infection.

In FY 1991, NIMH will continue to work with HRSA and their grantees. NIMH and HRSA will convene a meeting of staff in projects that are providing mental health counseling to discuss ongoing mental health counseling strategies. NIMH will provide technical assistance necessary to facilitate the integration of these mental health and counseling services into ongoing health care programs for this population.

Question. Given the fact that Congress has sought high quality research data about the value of mental health interventions, isn't it appropriate for NIMH to take the lead responsibility in funding this effort?

Answer. P.L. 100-607 stipulates that the Secretary, acting through the Director of NIMH, may provide technical assistance and administrative support to grantees under this provision of the legislation. NIMH has provided funds for these efforts in FY 1989, and has plans to provide funds for technical assistance efforts in FY 1990 and FY 1991.

NIMH is continuing to work with HRSA to assess ongoing mental health counseling efforts within HRSA AIDS Service Demonstration Projects. Such an evaluation will review ongoing mental health counseling and effective strategies and will identify existing gaps and needs.

NIMH also continues to take the lead responsibility to stimulate studies to identify successful mental health counseling approaches for individuals who are infected and affected by HIV and AIDS. An NIMH Prevention Workgroup Meeting in March 1990 will consider research data regarding the role of pre- and post-HIV antibody test counseling in preventing the further spread of HIV infection.

In the NIMH Health Care Worker Training Program, health and mental health care providers are being trained in pre- and post-test counseling techniques as well as the recognition and treatment of psychosocial and neuropsychiatric consequences of HIV infection and AIDS. AIDS mental health training is currently being integrated into the ongoing health care training being provided through the HRSA AIDS Education and Training Centers.

PREVENTION OF MENTAL ILLNESS

Question. A recent GAO report says that, as of a year ago, the national goals, priorities and programs for prevention of mental disorders and research on stress-related disorders that are required under federal legislation had not been established. The report notes that the Office of the Deputy Director for Prevention and Special Studies at NIMH does not have the resources or authority to carry out the prevention policies mandated by the law.

This concerns me for two reasons: one, that NIMH is failing to carry out Congressional direction and follow the law; and two, that the new initiative in rural mental health research and prevention may be similarly hamstrung by a lack of commitment of adequate resources on your part.

What has ADAMHA done to correct these serious deficiencies in prevention?

Answer. The National Institute of Mental Health (NIMH) is carrying out the Congressional direction and following the law. As part of its prevention strategy, the Institute has established the Office of Prevention and Special Projects, the Prevention Research Branch which funds prevention research in the mental disorders, and the Health and Behavior Research Branch, which funds research on stress related disorders. (The Health and Behavior Branch has been recently refocussed and retitled as the Basic Prevention and Behavioral Medicine Research Branch.) While the two research branches fund the major prevention research activities of the Institute, there are other significant prevention and prevention-related activities across the entire spectrum of the Institute, ranging from basic biological and behavioral investigator-initiated research to programs which have already proven quite effective in educating and informing the public. The Office of the Deputy Director for Prevention and Special Projects is responsible for coordinating all these efforts across the Institute.

The Institute will sponsor a series of annual state-of-the-art scientific conferences concerned with prevention of mental illness. The first of these conferences is scheduled for June 1990. Its purpose is to conduct a formalized audit of the status of the prevention research field and the solidity of the scientific foundation upon which preventive intervention research is currently based. The conference will provide a careful assessment of the field's status, research opportunities, and immediate and long term needs, including clinical and research training needs required to guide the Institute's next generation of prevention research activities. This will provide the Deputy Director for Prevention and Special Projects with the substantive information base for establishing and updating national goals, priorities and programs for prevention of mental disorders.

Concerning rural mental health, the NIMH is establishing an Office of Rural Mental Health as directed by the Congress to focus on this issue.

Question. The Committee provided new funding in FY 1990 for the Community Support Demonstration program, and set-aside $4 million for new prevention activities.

How will this $4 million be used in 1990?

Answer. The Community Support Program and the Child and Adolescent Service System Program currently support demonstrations of mental health programs which include prevention activities. NIMH will expand these efforts through the issuance of two new requests for applications (RFAs) shortly. One requests proposals for the prevention of youth suicide and suicidal behaviors in high risk groups. The other seeks studies on the prevention of conduct disorders in children and adolescents. Since these will be new initiatives for FY 1990, it is premature to estimate the final distribution of funding which will depend on the number and quality of applications received.

RURAL MENTAL HEALTH RESEARCH

Question. In FY 1990, this committee provided $10 million for a new program of research centers to focus on rural and Native American mental health. Please tell us what progress you have made on this initiative so far:

When can we expect the NIMH Office of Rural Mental Health to be fully operational?

Answer. The NIMH Office of Rural Mental Health will be fully operational as soon as a full-time Director can be recruited. The recruitment process has already begun.

To encourage applications for research projects focusing on mental disorders in rural populations, NIMH has issued a research program announcement--Research on Mental Disorders in Rural Populations. The receipt date for applications is June 1, 1990; initial reviews will be conducted during July, 1990; Advisory Council Review will be conducted in September, 1990; and funding will commence September, 1990. In addition, will issue a program announcement on epidemiologic and services research focusing on Native Americans, Native Hawaiians and Native Alaskans.

Question. How will the NIMH office coordinate with the Office of Rural Health Policy?

Answer. The major responsibility of the Office of Rural Health Policy (ORHP) is to work within the Department of Health and Human Services and with other Federal agencies, States, national associations, foundations and private sector organizations to seek solutions to health care problems in rural communities. The NIMH Office of Rural Mental Health is establishing working relationships with the Director and staff of the Office of Rural Health Policy by initiating dialogue on effective ways to pursue our complementary missions. These initial discussions have focused on: (1) the scope of activities of the respective offices; (2) mechanisms for sharing information through participation in ORHP and NIMH Advisory Council meetings; and (3) agreement to exchange information, memorandum, etc.

As NIMH builds its portfolio of research projects on rural mental health concerns, collaborative activities between principal investigators supported by NIMH and those supported by ORHP will be developed. One such activity will be development of teaching modules related to the NIMH D/ART (Depression/ Awareness Recognition and Treatment) program that can utilize the interactive satellite-based video communications system and data exchange established by ORHP at Texas Tech University.

Question. How many research centers will you fund in FY 1990 for rural mental health, and how many for Native American mental health research?

Answer. Since FY 1988, the NIMH has supported a rural mental health research center at the University of Wisconsin. In FY 1990, the NIMH hopes to fund an additional new research center on the subject of rural mental health.

Currently the NIMH does not fund any centers dealing primarily with Native American mental health and, thus far in FY 1990, no proposals for new research centers in this area have been received.

Question. What demonstration activities does NIMH have planned for FY 1990?

Answer. Research demonstrations (analogous to Clinical Trials of services interventions) are an integral part of the process of transferring the findings of basic and clinical research to those at risk for or already suffering from mental illness. NIMH has two major demonstration programs: the Community Support Program which includes demonstrations of services to children and adults; and the McKinney Homeless Demonstration Program.

NIMH will issue a requests for applications (RFAs) for services research demonstration projects focusing on prevention. The RFAs will emphasize prevention of youth suicide and the prevention of conduct disorders in children and adolescents. Institute efforts to demonstrate prevention interventions for depression, stress-related disorders and conduct disorder complement NIMH's suicide initiatives.

In FY 1990 NIMH will initiate new demonstrations of community-based crisis intervention and case management to prevent unnecessary hospitalization. These demonstrations are particularly suited to the special problems encountered by rural mental health delivery systems.

The McKinney Community Mental Health Services Demonstrations for Homeless Individuals program will competitively award $5.5 million in projects in FY 1990. Funded projects will incorporate research based evaluation components and cooperate in a national evaluation yielding cross-site information on implementation and effectiveness of interventions in this population.

Question. Will rural health and mental health experts serve on the peer review panels that evaluate rural mental health research and demonstration proposals?

Answer. Yes. In the identification and selection of reviewers, the single most important consideration is the specific expertise needed to fully evaluate the scientific and technical elements of the grant applications under consideration. When rural health or rural mental health issues are addressed in applications, individuals with such expertise are sought out and made part of the review committee.

PROTECTION AND ADVOCACY

Question. In FY 1987, Protection and Advocacy agencies handled over 14,000 cases for residents of mental institutions. Forty-five (45) percent involved neglect, 23 percent involved abuse, and 32 percent involved other rights such as access to legal representation.

In FY 1988, Protection and Advocacy agencies handled 23,000 cases for more than 15,000 clients. As in FY 1987, 45 percent of the complaints involved neglect, 23 percent involved abuse, and 38 percent of the complaints involved protection of legal rights.

Over two-thirds of the clients in FY 1988 were living in public mental health hospitals at the time they contacted the Protection and Advocacy agency.

To me, that says we need to continuing a strong federal program. Yet the budget requests a 43 percent funding cut for Protection and Advocacy in FY 1991, down from $14 million to $8 million.

Whose idea was this cut: what was your original budget request for Protection and Advocacy?

Answer. The President's FY 1991 Budget fully funds the Department's original request of $8.0 million for Protection and Advocacy. The decrease from the FY 1990 level represents the second year of a planned three-year phaseover to State responsibility. The Administration has proposed reduced federal funding in FY 1991 and FY 1992 to permit a transition to State and other sources of funding. No further Federal support would be provided beginning in FY 1993.

Question. Is there currently a backlog of unresolved Protection and Advocacy complaints, or are States all up to date on their caseloads?

Answer. The NIMH Protection and Advocacy (P&A) Program does not have information concerning the current day-to-day status of State P&A agency caseloads. The P&A Act does, however, require States to submit an annual fiscal year report of activities and accomplishments.

An "educated guess", based upon our knowledge of P&A operations, would be that there always is a backlog of unresolved P&A cases which State agency staffers are continuing to work on throughout the year.

ADMS BLOCK GRANT

Question. The Federal Government will contribute over $1.2 billion to States this year for substance abuse and mental health treatment through the Alcohol, Drug Abuse, and Mental Health Services (ADMS) Block Grant. Funding for the ADMS Block Grant has increased from just $600 million in FY 1987 to $1.2 billion this year, and the President's budget requests another $100 million for this Block Grant in FY 1991.

How would the budget request impact on the distribution of funds to the States for alcohol, drug abuse, and mental health treatment?

Answer. In FY 1987, $248.6 million (37 percent) of the block grant went to mental health services, and $423.1 million (63 percent) to substance abuse programs. In FY 1990, the ADMS block totaled $1,193 million. Of that amount, $237.6 million (21 percent) will be used for mental health services and $ 895.7 million (79 percent) will be used for substance abuse programs. The FY 1991 President's budget requested an additional-$100 million to be used for drug abuse services only. This funding level will be added to the current

$1.2 billion appropriated for FY 1990 to enhance the provision of drug abuse treatment and prevention services and add to the expansion of capacity to meet the States highest priority needs at the community level. These additional funds will be allocated to States in the same proportion as provided by the Congressionally-mandated formula used in FY 1990. Of the $100 million, $10 million will be earmarked specifically for data collection and program evaluation activities. The resulting distribution in FY 1991 will give mental health $237.6 million (19.5 percent), and $981.0 million (80.5 percent) for substance abuse programs.

COMMUNITY SUPPORT DEMONSTRATIONS

Question. The Community Support and Child and Adolescent Service System Programs are designed to improve systems for service delivery to severely emotionally disturbed adults, children, and adolescents.

What was the rationale for proposing a cut in funds for these demonstrations in FY 1991--are the programs no longer successful in demonstrating new models for providing mental health services?

Answer. The proposed funds for the Child and Adolescent Service System Program (CASSP) reflect an increase for FY 1991. However, the proposed funds for the Community Support Program (CSP) are decreased by $2 million. This is not because the models being demonstrated are not successful. To the contrary, many are demonstrating positive outcomes for the population, and States are continuing these programs with State funds as the 3-year Federal demonstration funds end. The FY 1991 budget request will support continuation costs for all current CSP/CASSP projects and support approximately 26 new grant awards, including 10 new State-wide service system improvement projects. In addition, staff will continue to work with States and communities in a technical assistance and consultation capacity to stimulate the development of effective services emphasizing assistance to those at high risk of becoming homeless.

Question. What is the estimated population in need of these services?

Answer. NIMH estimates that there are approximately 2.7 million individuals in the Nation afflicted with severe and persistent mental disorders who need mental health and community support services in order to live productive lives.

NIMH research and research-based demonstrations will add valuable knowledge to State and local based systems that care for persons who are seriously mentally disabled.

DISSEMINATING RESEARCH FINDINGS

Question. In rural areas, it's generally the nurse or doctor, not the substance abuse specialist, who first sees someone that's having a problem with alcohol or drugs. This is often the case with mental health problems, also.

What is ADAMHA doing to make research findings available to these health practitioners in rural areas, such as the database of findings on the signs and the effects of alcohol and drug abuse?

Answer. In collaboration with NIAAA, NIDA has supported the development of alcohol and drug abuse curricula and clinical training for primary care physicians and nurses. These programs train health professionals in the diagnosis and treatment of alcohol and drug abuse. In addition, NIDA has cooperated with HRSA's Bureau of Health Care Delivery Assistance to provide training in drug abuse and AIDS to health care professionals. NIDA has also worked with HRSA to integrate drug abuse services within the primary health care system.

In FY 1990 NIDA is collaborating with NIAAA and OSAP to make clinical training awards for 'Faculty Development in Alcohol and Other Drug Abuse.' This program will provide funding to support the development of faculty in schools of medicine, nursing, social work, and departments of psychology. A major emphasis will be on providing primary care training opportunities on the application of drug abuse research to clinical education and practice.

Rural health practitioners are being served through the Office for Substance Abuse Prevention's RADAR (Regional Alcohol and Drug Awareness Resource) Network, which is OSAP's primary communications vehicle at the State and regional level. Each State RADAR Network Center is responsible for disseminating alcohol and other drug (AOD) information to its various target audiences through a variety of communication channels. OSAP's National Clearinghouse for Alcohol and Drug Information makes available to each of the State RADAR Network Centers bulk copies of publications that are specifically targeted to health practitioners on topics such as professional education, fetal alcohol syndrome, or alcoholic hepatitis; or for their patients on a wide variety of AOD topics.

Question. How does NIMH get information out to the public, and out to mental health practitioners -- is there a clearinghouse at NIMH similar to the ones at NIAAA, NIDA, and OSAP?

Answer. The Office of Scientific Information (OSI) is responsible for disseminating information about mental illnesses, their prevention and treatment, to the public and mental health practitioners. The OSI communicates with the print and broadcast media, holding press conferences, issuing news releases, and providing background information on current topics. Articles are written for publication in Hospital & Community Psychiatry, the Journal of the American Medical Association, and other journals. Articles on mental health topics are disseminated to local and rural newspapers. NIMH pamphlets, brochures, and monographs for the public and mental health practitioners are written by OSI staff and other components of the NIMH.

The Information Resources and Inquiries Branch (IRIB), OSI, disseminates information to the public by answering over 100,000 inquiries per year, distributing more than 300,000 copies of NIMH publications, providing for the availability of selected NIMH publications in supermarkets, and maintaining a file of information resources. In addition, this branch ensures that knowledge of NIMH publications is available through flyers, notices in journals and newspapers, and sale at the Government Printing Office.

Question. What is the NIMH budget for activities relating to dissemination of research findings?

Answer. Dissemination of research findings is an integral part of every scientific program in the Institute. We cannot readily compute the full amount of funds devoted to this activity, but we can provide a rough estimate of extramural funding based on the sum of the figures for the Office of Scientific Information; the Depression/Awareness, Recognition and Treatment program (D/ART); all scientific publications of the various Institute components; and all scientific conferences and workshops. That total is $5.3 million. The Intramural Program findings are widely disseminated through peer reviewed journals, presentations and poster sessions at meetings, and talks and publications by many intramural scientists which are aimed at lay audiences.

Question. Last year the Committee expressed concern over the low level of effort devoted to services research, and encouraged NIMH to fund and promote research in such areas as preventive mental health services, the delivery of services for the seriously mentally ill, and the role of family and community factors in the mental disorders of children and adolescents.

What has the Institute done in response to this request?

Answer. The NIMH has significantly increased its investment in services research with the aid of additional funds made available through the Anti-Drug Abuse Act of 1988. New and revised announcements were issued last year to invite applications for research on mental health services for children and adolescents, adult severely mentally ill persons, homeless mentally ill persons, mentally ill persons with co-occurring substance abuse disorders, patients with HIV infection, reimbursement of mental health services, and a center for research and knowledge dissemination on self-help mental health services. Other announcements invited States to submit applications for grants to improve their mental health statistical data collection programs and to evaluate their service delivery programs. The NIMH services research grants program increased from $9 million in FY 1988 to $24 million in FY 1989 as a result of the numerous high quality applications received from researchers and State mental health agencies. Research on services for children and adolescents increased from $1 million to $4 million.

In FY 1991 the NIMH plans to issue two new announcements inviting applications for research demonstration projects on preventive services. These will be concerned with the prevention of youth suicide and suicidal behavior and with the prevention of serious and chronic conduct problems during childhood, adolescence, and early adulthood (e.g., severe conduct disorder, chronic delinquency, violent behavior, antisocial personality disorder).

AIDS FUNDING IN NIMH

Question. You indicate that the AIDS research portfolio is equally balanced between behavior change and prevention on the one hand, and neuroscience on the other. It appears, however, through review of the NIMH justification, that while extramural research funds are balanced between neuroscience and behavioral research, virtually all of the intramural research activity is focused on neuroscience.

I don't see a balance there. Please justify this discrepancy.

Answer. The balance between behavior change and prevention, on the one hand, and neuroscience on the other, is in the total NIMH research effort. In FY 1990, $21.95 million is estimated for biomedical and neuroscience research, compared to $28.12 million for behavioral research. In FY 1991, $23.93 million is requested for biomedical and neuroscience research (a 9 percent increase) compared to a $33.74 million request for behavioral research (an increase of almost 20 percent).

NIMH has been placing increased emphasis on the area of behavior change and prevention research in AIDS extramural research. The Intramural Research Program focuses primarily on neuroscience research.

Question. The research portfolios at NINDS and NIAID have significant components addressing AIDS neurovirology, psychoneuroimmunology, and pathogenesis of the HIV virus.

Given that no other agency within the Public Health Service is responsible for identifying effective prevention strategies to prevent AIDS, how do you justify allocating less than half of the NIMH AIDS research budget to prevention?

Answer. NIMH has been placing increasing emphasis on AIDS prevention research. Currently, approximately 56 percent of the NIMH AIDS basic science research effort focuses on behavioral research. Most of these projects are related to the development of AIDS prevention strategies.

NIMH shares the prevention mission with CDC and HRSA. In March 1990, NIMH is cosponsoring a meeting on prevention with NIDA, CDC, and HRSA. Representatives from OSAP will also attend. The purpose of the meeting is to review AIDS prevention efforts in research, training, and services. Gaps in prevention activities will be identified and strategies will be recommended for facilitating the dissemination of AIDS prevention research findings to clinical and community settings. Collaborative approaches for more effective linkage of AIDS research, training, and services will be explored.

Several initiatives are underway to expand AIDS prevention research efforts, including: (1) a cooperative agreement for a coordinated multi-site, multi-population AIDS prevention trial, and (2) a meeting of NIMH-supported AIDS prevention researchers to recommend research priorities for AIDS prevention.

USE OF BLOCK GRANT SET-ASIDE FUNDS

Question. Under the law, five percent of the funds allocated to the Alcohol, Drug Abuse, and Mental Health Services block grant are set-aside for the Department to use to provide technical assistance, collect data, and for other activities. In FY 1990, the 5 percent set-aside comes to almost $60 million.

What are you planning to do with this money?

Answer. In FY 1990 ADAMHA proposes to use 5 percent or $59,643,000 of the ADMS Block grant to collect data, perform services research and provide technical assistance.

Efforts begun in FY 1989 will be continued in FY 1990 and will consume approximately 70 percent ($42 million) of the available resources. New efforts approximating $13 million are planned.

Tentative distribution by category:

Data Collection:	$41,211,000
Services Research:	16,432,000
Technical Asst:	2,000,000

In response to Senate Report #101-127, ADAMHA described how funds were used in FY 1989. In addition to continuing a number of those projects, the following new projects are planned:

> A National Treatment Unit Description Study will be funded by NIAAA that will provide detailed information about the characteristics of treatment in a nationally representative sample of treatment units and clients.
>
> Replication Studies. A contract to be awarded by NIAAA will create a mechanism by which promising studies of treatment effectiveness can be replicated to assess the validity and robustness of findings.
>
> In-Utero Drug Exposure Survey. NIDA will survey a nationally representative sample of mothers who have delivered infants in hospitals about their drug use previous to and during pregnancy. The survey will provide reliable and comprehensive data on in-utero drug exposure, including prevalence of drug use during pregnancy , estimates of the number of newborns who are exposed to drugs during pregnancy and characterization of exposed infants and their mothers.
>
> NIDA will conduct a national health interview survey on the patterns and consequences of marijuana and cocaine use that allow for correlation of data on the incidence of acute illness and injuries, prevalence of chronic conditions, extent of disability, and the utilization of health services.
>
> NIDA will also begin a Substance Abuse Coverage Study, that will determine the extent and adequacy of coverage for substance abuse services in existence. The study will look at the quality, cost, and effectiveness of treatment.

The Metropolitan Area Survey will be expanded to cover six additional cities. The study will demonstrate that a comprehensive data collection system can be developed for estimating the prevalence, incidence and consequences of drug abuse in a metropolitan area.

Question. What technical assistance activities are planned?

Answer. In FY 1989, the ADMS Block Grant set-aside was $40.28 million, of which $1.5 million funded technical assistance activities.

ADAMHA used this money to conduct the first National Alcohol, Drug Abuse, and Mental Health Conference for Adolescents. In addition, ADAMHA funded 12 States to disseminate successful State programs in the areas of block grant management, supported housing, services to minority populations, and improved assessment of and service delivery to dually-diagnosed populations. ADAMHA also used technical assistance money to contract with Oxford House to provide support to the States in the establishment of group homes for recovering substance abusers.

For FY 1990, the set-aside will be $59,643,000 of which $2 million is for technical assistance.

ADAMHA plans for these funds include the holding of six workshops in the following areas:

Needs Assessment
Homeless
Outcome Measurement
Coordination of Service
Drug Abuse Treatment for Women
Criminal Justice Coordination

In addition to the workshops, plans call for the establishment of a cadre of experts called The Treatment Improvement Exchange, to be available for on-site consultation with States around ADM service delivery problems; writing, printing and dissemination of monographs on all aspects of service delivery; to support a process to help States strengthen their drug treatment plans; and the design and implementation of an on-site Management Review program to assess State performance and determine State-specific technical assistance needs.

Question. How will these set-aside funds help us get a clear picture of the nature and scope of substance abuse and mental health problems in the States in the country as a whole?

Answer. The primary use of block grant set-aside funding is to assist the States in administering the block grant funds through technical assistance, evaluate existing treatment programs through services research, and perform data collection activities essential to effective use of the ADMS block grant funds. Our experience since FY 1989 however, has been that as a sub-set of assistance to the States and through review of data collection efforts, we at the

Federal level are gaining a better understanding of the nature and scope of substance abuse and mental health problems. Several efforts highlight this phenomenon.

Availability of timely, accurate, uniform and comprehensive services systems data is essential to policy, planning, and research efforts. Thus, initiatives designed to extend the Nation's capacity to collect mental health and substance abuse/patient/client data and systems data received considerable attention under the block grant set-aside. A key component of the NIMH program was a special grant program designed to allow State mental health agencies to upgrade data systems to meet standards embodied in the joint Federal-State Mental Health Statistics Improvement Program (MHSIP). The objective was to allow a stronger foundation for services research.

The on-going National Household Survey on Drug Abuse provided data on the incidence, prevalence, trends and correlation between drug and alcohol use in a representative sample of the United States. Set-aside funds available for the first time in FY 1989 allowed the survey to be revised for FY 1990 to obtain responses from hard-to-reach populations, and expanded it to additional metropolitan areas.

The National Drug and Alcoholism Treatment Utilization Survey (NDATUS) provided a census of all alcohol and drug abuse treatment and prevention programs available nationwide.

The National Longitudinal Alcohol Epidemiology Survey is performed through an interagency agreement between NIAAA and the Bureau of the Census. In this survey we collect information on the quantity, frequency, and patterns of alcohol use, and the prevalence of alcohol and selected drug use disorders and associated disabilities.

To learn more about the co-occurrence of mental disorders and alcohol and/or drug abuse, a research grant was awarded to assess its prevalence. Also, seven research grants were awarded for studies of service delivery to persons with both mental and substance abuse disorders.

STATES' COMPLIANCE WITH THEIR STATE PLANS

Question. The ADMS block grant will allocate about $1.2 billion to States for alcohol, drug abuse, and mental health services in FY 1990. As the block grant has become larger and more complex in recent years, ADAMHA has decreased the amount of staff and the support budget for the program, and has not allocated funding for oversight.

There are some indications that a lack of adequate oversight and technical assistance by ADAMHA has resulted in States not complying with statutory requirements under the law for spending block grant funds: for example, States are required to use at least 50 percent of their drug treatment funds for IV drug abuse, and must use at least 10 percent of total ADMS funds for programs for women.

GAO visited three States to determine whether they were in compliance with several drug treatment provisions, and found they weren't--even though they had assured HHS in their applications that they were complying with these provisions.

How will ADAMHA ensure State's compliance with mandated spending requirements, and what oversight activities are planned for FY 1990 and FY 1991?

Answer. Applications for ADMS Block Grant funds must contain an assurance that the State will comply with all legislatively mandated requirements. Each State must also be subjected to an independent audit yearly. These audits are concerned with both fiscal and compliance issues and would uncover any use of funds not authorized by law.

In addition ADAMHA continues to oversee the program through a compliance review process. Under this process selected States submit documented responses to questions about how the ADMS Block Grant requirements and set-asides are met. ADAMHA staff review the documents provided and determine if the State is in compliance, more information is required, or if an on-site review is necessary.

ADAMHA staff are also designing an on-site Management Review program to assess over-all State performance toward meeting mandated spending requirements and determining State-specific technical assistance needs. These on-going and planned activities will go a long way toward improving oversight of the ADMS Block Grant program.

Question. What resources will you provide to oversight and technical assistance in FY 1991?

Answer. In FY 1991, assuming the President's budget is accepted and the authorized set-aside is the proposed $74,139,000 approximately $2,191,000 of that money will be available for technical assistance.

The Office for Treatment Improvement (OTI) is responsible for the administration of the ADMS Block Grant. OTI is in the process of staffing up to their authorized level. In addition to the full-time OTI staff assigned to this program, approximately 30 other staff and outside consultants will provide oversight and technical assistance on a part-time basis.

CLINICAL TRAINING

Question. We have been concerned in the past about ADAMHA's use of clinical training funds, both how funds appeared to be spread among the disciplines unevenly, and how only some recipients of clinical training funds have fulfilled their requirement of a service payback.

What would be the impact of the proposed 63 percent cut in clinical training funds from $13.5 million down to $5 million on numbers of professionals trained?

Answer. The NIMH does maintain a system which provides data on the number of trainees and the number of trainee appointments but, unfortunately, this data is recorded by the calendar year of first appointment and/or reappointments and not against the fiscal year of actual obligation. To the best of our knowledge, therefore, we can only estimate that the impact of the reduction in Clinical Training funds would be to reduce the number of professionals trained by approximately the same proportion.

Question. How are clinical training funds allocated among the core disciplines?

Answer. The Clinical Training funds are initially allocated equally among the core disciplines. However, the grants funded are based on scientific merit.

For FY 1989, NIMH clinical training grants were funded among the core disciplines as follows: Psychiatry, $1,889,000; Psychology $2,003,000; Social Work $1,893,000; Nursing $1,226,000; and Multidisciplinary $449,000.

Question. Describe the clinical training initiative for rural mental health providers.

Answer. Two clinical training requests for application (RFAs) were issued in FY 1990 by NIMH: Institutional Clinical Training and Individual Faculty Scholar Awards. Both of the these emphasized rural mental health as a cross cutting priority. The intent is to recruit trainees from rural areas and increase the supply of rural mental health providers. In addition to the grant mechanism, contracts are used to support projects focused on rural mental health education.

Recent survey research has indicated that farm families rank stress next to chemical exposure as their most significant health concern and that some 21 percent of rural residents report significant levels of depressive symptomatology. The Depression Awareness, Recognition, and Treatment (D/ART) Program of NIMH is a national effort to educate the public; primary care physicians; and mental health specialists about depressive disorders--their symptoms and treatment. The program is a public/private partnership linking professional and lay mental health agencies and groups, business, government, professional organizations and service providers for a common purpose. In addition, D/ART professional training grants support short-term training activities for health and mental health practitioners on diagnosis and treatment of clinical depression.

Of note among the D/ART professional training grants are programs in States with substantial rural populations: Indiana, Minnesota, Illinois, Utah, Vermont, Michigan, and Iowa. The University of Iowa Clinical Training in Diagnosis/Treatment of Depression project provides continuing education regarding epidemiology and assessment of depression, psychological and biological perspectives on its etiology, psychological and biological interventions, case management and special populations particularly affected by depression. Several methods of instruction are used, including lectures, audio-visual presentations and group discussions. The trainees will be 360-600 health and mental health professionals who practice in rural and agricultural areas affected by the farm crisis, primarily in Iowa. The program will be offered at 6 sites.

The faculty is multidisciplinary and includes psychology, nursing and psychiatry. The training provided is expected to increase the ability of the participants to diagnose and treat depression appropriately.

Because a primary care physician often is the only professional available in many rural areas, D/ART training being conducted at the University of Minnesota focuses on accurate assessment and management by primary care physicians of major depression in adults. Other University of Minnesota training programs emphasizing adolescent depression have been targeted to school personnel, psychologists, and social workers as well as pediatricians and family practitioners.

At the University of Utah, the Mountain West Project is expected to train over 500 health and mental health practitioners from Utah, Idaho, Montana and Wyoming. The core training concentrates on either the treatment of adults or the treatment of adolescents. These activities represent significant movement toward improving, for broader segments of the population, the diagnosis and treatment of depression.

Question. Are you addressing the Conference Committee's concern about students paying back their funding through public service by requiring all students to payback?

Answer. Yes, the NIMH has addressed the issue of students paying back their funding through public service by requiring all students receiving support for longer than 180 days to payback.

Beginning in FY 1989, the Request for Applications (RFAs) for all Institutional Training grants issued by the NIMH clearly states that the sole purpose of such grants is for trainee stipend and tuition support in which the trainee incurs a payback obligation.

REDUCING TRANSMISSION OF AIDS

Question. What programs does ADAMHA have to reduce HIV transmission by IV drug abusers through means other than needle-sharing; what programs reduce transmission by drug users who are not IV users?

Answer. The National Institute for Drug Abuse (NIDA) is funding several forms of treatment, including various forms of individual, group and family psychotherapy; behavioral therapy such as contingency management; extinction procedures and aversive conditions; social skills training; relapse prevention; self-help group strategies; and counseling techniques.

NIDA is currently funding two studies of acupuncture to determine its effectiveness in the treatment of drug abuse.

OFFICE FOR TREATMENT IMPROVEMENT

Question. Last year, ADAMHA created a new Office for Treatment Improvement.

What do you hope to accomplish through this office, and what will this office do to evaluate different treatments, disseminate that information, and provide technical assistance to treatment programs to organizations that are trying to improve their programs?

Answer. OTI's mission is to improve the overall quality of drug treatment services nationwide. During its initial year in operation, OTI will use its $72 million in discretionary funds for several programs. OTI also provided $40 million in Waiting List Reduction Grants to help alleviate the national shortage of drug treatment slots and services.

OTI provides comprehensive financial assistance to selected cities to improve the overall quality of drug abuse treatment services. Special emphasis will be placed on helping these cities develop or strengthen central intake and referral capabilities, improve treatment programs, expand post-treatment services and follow-up, and augment program evaluation.

Funds are also used to support treatment improvement efforts of programs serving populations with critical needs, with a focus on ethnic minorities, adolescents, and residents of public housing. OTI also strengthens drug abuse coordination with State and local correction systems including selected funding of projects that encourage individuals convicted of drug related crimes to seek treatment in lieu of incarceration, augmenting drug treatment services in prisons and correctional facilities, or strengthening management of drug treatment for released individuals by parole officials.

In addition, OTI will work with NIDA to identify information from NIDA treatment efficacy research that is ready for dissemination to State and local drug treatment administrators and clinicians. OTI will sponsor workshops, conferences, and prepare "hands-on" written material to assist the treatment community in adopting proven treatment modalities identified through NIDA basic, applied and clinical research.

Question. By what methods will OTI evaluate treatments to determine their effectiveness?

Answer. All programs OTI funds will have strong evaluation components, thereby enabling OTI to disseminate the results of these demonstration activities. Evaluation methodologies will be established as part of each program as it is developed.

OTI is working with State drug abuse authorities to install a voluntary system of annual States Substance Abuse Service Planning. Through this process, OTI will encourage States to improve the quality and accountability of the public treatment system by strengthening State planning and management. OTI will conduct State management reviews and provide technical assistance to States to help them improve administration of federal and State drug abuse activities.

Question. How will this office help smaller programs, such as the ones in my home State of Iowa, get up to speed on treatments of proven effectiveness?

Answer. During FY 1990, OTI will sponsor a series of six technical assistance conferences for State and selected local drug abuse treatment officials. This conference will focus on drug treatment for the homeless, special treatment services for women, assessing needs for drug abuse treatment services, performance criteria for assessing treatment effectiveness, coordinating drug abuse treatment with other needed medical, social, educational and vocational services at the State and local levels, and improving coordination between community drug treatment and the correctional system.

OTI will establish a national consultant exchange program through which State and local treatment providers may obtain the services of specialists and clinicians with particular expertise to help design and improve their treatment programs. Through this consultant program, the Treatment Improvement Exchange, it is envisioned that approximately 300 such experts will be identified and made available with federal funds during FY 1990 and FY 1991. The effectiveness of this exchange program will be evaluated with intensive follow-up to determine the degree to which the experts were helpful to those seeking assistance and the nature of change or improvement in treatment efforts that resulted from on-site technical assistance.

OTI plans to develop, through consensus efforts, treatment standards and guidelines for use by State and local programs. A high priority during FY 1990 will be the development and dissemination of guidelines for measuring the effectiveness of treatment programs, or program "performance criteria." OTI will also develop standard definitions for use by the field, such as what comprises "comprehensive treatment services."

INTERGOVERNMENTAL COORDINATION TO FIGHT DRUGS

Question. The President's drug control plans call for increasing Federal, State, and local coordination, and for making treatment programs more accountable.

What steps have been taken to implement the recommendation from the President's National Drug Control Strategy for greater State, local, and individual treatment program accountability for effectiveness?

Answer. ADAMHA has taken a number of actions to effect treatment accountability by Federal, State, and local governments in the administration of Alcohol, Drug Abuse, and Mental Health services delivery programs. These actions have emphasized cooperation between the different organizational levels and between different components dealing with the ADM problems, such as Justice and Education Departments. They go beyond the Governor's assurance that a State will meet the requirements and restrictions of the law, the holding of public hearings on the intended use of the funds, and yearly audits for both programmatic and fiscal compliance.

For example, ADAMHA oversees program accountability through a compliance review process. Under this process selected States are subjected to an on-site review for compliance with the mandated requirements of the law. ADAMHA staff is also designing an on-site

Management Review process to assess over-all State performance and to determine State-specific technical assistance needs.

Future activities to improve coordination and treatment program accountability include the holding of technical assistance workshops on Needs Assessment, Coordination of Services, Criminal Justice Coordination, and Outcome Measurement. ADAMHA will obtain input from National organizations and State and local ADM Directors on both the design and execution of all future activities.

ADAMHA staff has been working with the National Association of State Alcohol and Drug Abuse Directors and several State Directors to develop a voluntary State Drug Treatment Plan that will include coordination and outcome measurement components. This voluntary activity underscores the readiness of ADM service providers to increase coordination and program accountability.

Lastly, two ADAMHA programs have specific focus on coordination of community services to enhance intervention effectiveness. The Office for Substance Abuse Prevention (OSAP), through its Community Partnership Demonstration Program, provides long-term, multidisciplinary resources to assist communities in developing comprehensive, collaborative, and systematic approaches which emphasize local community involvement, systems, and environmental changes reflecting that community's values and institutions. OSAP's Pregnant Women and Infants program is designed to develop innovative, community-based models of education, prevention, and/or treatment, for substance abusing women and their infants. These demonstration grant programs are designed to promote the coordinated participation of multiple organizations in the delivery of comprehensive services for substance using pregnant and postpartum women and their infants.

Question. What are the States doing to implement the President's call for improved coordination between treatment facilities and social, employment, and health agencies in order to assist drug-dependent people with the range of services they need; and what is ADAMHA doing to assist States in this effort?

Answer. There is an increased recognition among State drug abuse treatment officials that drug-dependent individuals require a variety of services and supports in addition to drug treatment services, if the effectiveness of drug treatment is to be improved. Although ADAMHA does not now have systematic and comprehensive information about what all the States are currently doing to increase the coordination of these services, it has initiated several activities to help States strengthen the coordination of needed activities.

For example, in early 1989, ADAMHA co-sponsored, along with the Departments of Education, Justice, three Anti-Drug Abuse Seminars for State officials responsible for drug abuse education and justice programs. These seminars involved hundreds of State officials and encouraged the strengthening of coordination in States and localities. Numerous participants credited these seminars with fostering greater interaction and coordination.

Later in 1989, ADAMHA initiated a small study to review the state-of-the-art of coordination for alcohol, drug abuse, and mental health services. An early draft of this review will be the topic of a one-day meeting with about six State officials in the spring of 1990, to be followed by a second small meeting. ADAMHA will soon announce a national technical assistance conference, to be held in the spring of 1991, to help State officials focus on techniques to improve the coordination of drug treatment and related services and supports.

With the creation of the Office for Treatment Improvement (OTI), ADAMHA will further foster improved coordination through a voluntary State planning process. Among other things, States will be asked to describe their current efforts to coordinate needed services and to indicate the need for technical assistance. Based on these findings, OTI will provide extensive on-site management reviews and a national Treatment Improvement Exchange that will provide individuals with relevant experience and expertise to help States requesting assistance.

OTI is supporting initiatives to mainstream drug treatment into the health care system, to improve drug treatment for those incarcerated in jails and prisons, to increase the availability of group homes and other kinds of supported housing, and to strengthen the development of a variety of coordinated services and systems needed to provide and enhance the efficacy of drug treatment in selected target cities.

OTI will also fund treatment improvement demonstrations in approximately 6 urban jurisdictions this year. Total funds available for this program are approximately $28 million for FY 1990 and an estimated $32 million in FY 1991. The primary goal of this program is to implement overall systemic improvements in metropolitan settings.

OSAP initiated, in FY 1990, with funds provided by P.L. 101-164 and P.L. 101-166, the community prevention (partnership) program is designed to stimulate the formation of local coalitions, consortiums and partnerships for the purpose of developing comprehensive, multidisciplinary drug abuse prevention systems. This program promotes sound, long-term prevention systems by creating a forum through which local interests, including parents, youth, representatives from business and industry, religious institutions, civic groups, health care agencies, local governments, and other organizations can work together to implement community-wide alcohol and other drug abuse prevention and treatment initiatives.

IV DRUG TREATMENT CAPACITY

Question. The 1988 Anti-Drug Abuse Act requires States to respond to reports from local drug abuse treatment programs that have reached 90 percent of capacity with assistance to ensure treatment services within seven days for any IV drug abuser who requests treatment.

How are States implementing this requirement?

Answer. All States were required to provide an assurance in their application for FY 1989 funding under the ADMS Block Grant that the State would implement this provision. Each State has provided that certification.

ADAMHA has provided technical assistance to the States on all aspects of the block grant legislative requirements including discussion on the importance of this particular provision. Meetings were held with a variety of State officials during 1989 at the following locations: Washington, D.C., Alexandria, Virginia, San Antonio, San Francisco, Indianapolis, Des Moines, and St. Louis. ADAMHA also discussed this matter with State representatives and staff from the National Association of State Alcohol and Drug Abuse Directors, the National Association of State Mental Health Program Directors, and the Alcohol and Drug Problems Association of North America.

ADAMHA provided funding totalling $100 million in FY 1989 and FY 1990 to implement the Drug Abuse Treatment Waiting List Reduction Program to enhance State capacity to provide treatment services to high priority populations. Virtually all of the funded entities served community-based programs with high percentage utilization rates, often to provide services to IV drug abusers within the seven-day period referred to in this provision.

Finally, the State is statutorily required to report annually to the Secretary on how the State has carried out the provisions of the Block Grant legislation. The annual report covering activities of the State for FY 1989 is to be submitted by States within the next several months. Specific information on how each State has implemented this provision will be available approximately July 1990.

SUBSTANCE ABUSE COUNSELORS

Question. We vastly increased funding in FY 1990 for training substance abuse counselors. How many substance abuse counselors and other alcohol and drug abuse health professionals will be trained by OSAP programs in FY 1991?

Answer. A significant amount of new funds was provided in FY 1990 for the training program, with the largest single block of these funds designated for substance abuse counselor training. Under this initiative, approximately 20 contracts will be awarded to various training and educational organizations to provide training for entry level substance abuse counselors in the first year, and advanced training for practicing counselors in the second and third year. In FY 1991, OSAP expects to support the training of 3,500 new counselors. Another 3,500 existing counselors will benefit from brief skills-enhancement seminars.

Other health professionals such as physicians and nurses are being trained through a variety of OSAP National Training System cooperative efforts. For example, one effort will pilot and provide training materials for all the primary care providers in the over 600 community health centers and migrant health centers across the country. Another cooperative effort is with Brown University for the development and piloting of physician continuing medical education module and, through the 600 physician members of the American Society of Addiction Medicine (ASAM), the training of physician trainers for this effort. Dissemination of these modules will be made to all AMA members. OSAP will sponsor training for over 6,000 physicians, nurses, social workers, and other primary care providers in FY 1991.

While this adds to over 13,000 OSAP sponsored trainees, it actually will be greater when considering the thousands to be reached through dissemination of training materials upon request.

HOMELESS

Question. What is the planned FY 1991 level of support for programs that serve the homeless? What support will be given to the homeless in rural areas who are mentally ill or substance abusers?

Answer. The FY 1991 President's Budget requests $72,069,000 for Homeless programs throughout ADAMHA. That funding is split between the McKinney Programs (Mental Health Services to the Homeless Block Grant, and Mental Health and NIAAA Homeless Demonstrations) and the homeless demonstrations in the non-McKinney Community Support Program.

In NIAAA, the Alcohol and Drug Homeless Research Demonstration program will provide 18 awards at $9,498,000. The target population of this program primarily includes all homeless persons and those at imminent risk of becoming homeless who have alcohol and/or other drug problems. These research demonstration projects are intended for location in urban centers with populations greater than 250 thousand persons or in less populated areas where the applicant for an award can demonstrate evidence of sufficient members of the target population to permit a rigorous evaluation design.

ADAMHA plans $33,703,000 for the MHSH Block Grant Program which provides funds to all States, the District of Columbia, and the Territories for mental health services for the homeless. These funds are allotted according to a formula, based on the proportion of a Sates' population in urbanized areas relative to the total national population in urbanized areas. The President's budget provides a 21 percent increase for this program over FY 1990.

Mental Health Services Demonstrations Projects amounting to $6,006,000 are also planned. These projects are intended to develop and evaluate comprehensive service systems for homeless mentally ill individuals. In FY 1991, NIMH anticipates awarding approximately 24 grants.

In addition to the McKinney programs described above, NIMH administers the Community Support Program. We plan to award $22,862,000 in grants that promote the development of effective, comprehensive, community-based systems of care for adults with severe and persistent mental illness. State Service System Improvement Projects encourage States and communities to give greater priority to the needs of those who are homeless or living in unstable housing situations.

Additional to the programs described above, NIMH conducts an on-going research program on homelessness and its relationship to mental illness. The purpose of this initiative is to accelerate the development of knowledge that can contribute to more effective delivery of mental health services to homeless adults and homeless families and children. In FY 1991, NIMH will make third year continuation awards to 10 research and research demonstration projects and second year continuation awards to 6-8 grantees.

One of these FY 1991 third year continuation awards will support research focused on rural homelessness. This grant "Rural Homelessness in Ohio: A Five-Year Study" will identify changes in the size and characteristics of rural homelessness; develop additional knowledge about the causes of rural homelessness, estimate the prevalence of mental illness among the rural homeless in Ohio; and study service access and utilization among the homeless mentally ill population.

To encourage expanded research in the area of rural homelessness, the NIMH will issue a new research announcement in FY 1990 on the mental health needs of rural persons with special emphasis on the mental health needs of the rural homeless population. This new announcement will be in addition to the current NIMH homeless research announcement which also encourages studies of the mental health needs of rural homeless persons.

PAYMENTS DON'T FOLLOW PATIENTS

Question. What proportion of federal dollars spent on mental health treatment is spent on inpatient versus outpatient?

Answer. Data from the NIMH national reporting program indicate that in 1986 organizations that provide mental health care received an estimated $4.9 billion in Federal funds. Approximately $4.1 billion (84 percent) was received by organizations that primarily offer inpatient or residential care (e.g., State hospitals, non-Federal general hospitals). The balance, approximately $0.8 billion (16 percent), was received by organizations that primarily offer ambulatory care (e.g., psychiatric outpatient clinics, multiservice mental health organizations).

BEHAVIORAL RESEARCH

Question. Dr. Goodwin, your budget justification notes the major issues of concern to the House and Senate Subcommittees, and is supposed to outline ADAMHA's response to those concerns.

Yet I note your budget justification ignores all the Senate report language on behavioral research. That language cites reports issued in the last year by the National Academy of Sciences and others recommending that NIMH spend more on behavioral and social science research and training. For example, National Academy of Sciences reports call on ADAMHA to devote $80,000,000 more per year to behavioral and social science, which is ripe for major breakthroughs, and to commit significant additional funds to study psychological, behavioral, and social interventions aimed at stemming the AIDS epidemic.

The Committee also directed the Director of NIMH to report back to us on plans to increase the behavioral and psychologic presence at NIMH.

What can you report?

Answer. NIMH continues to meet its responsibility as the focal point for Federal Government social and behavioral research in the mental illnesses. NIMH is finalizing a thorough report on "Behavioral and Social Science Research at NIMH" in response to the request contained in the FY 1990 Appropriations Committee Bill Report which will be available shortly.

Whatever their fundamental causes, mental illnesses manifest themselves as disorders of behavior. The growth of the basic brain sciences in the Institute's research program is only part of the coordinated effort to address mental illnesses. In fact, from FY 1984 through FY 1989, funding for research with a primary behavioral or social science focus has increased 106 percent. Major NIMH research programs have been initiated anticipating the findings of the National Academy of Sciences and other studies and more are being implemented or developed to respond to external and internal recommendations.

NIMH is the focal point within the Public Health Service for AIDS research both on behavior and its psychological and psychosocial determinants, and on primary prevention to modify high risk sexual behaviors. The Institute has undertaken a series of activities to foster programs of basic and applied social and behavioral research relevant to HIV infection and AIDS. In FY 1989, slightly more than half of the grants in the NIMH AIDS program were behavioral research projects. The FY 1990 and FY 1991 NIMH AIDS budgets continue this level of support for behavioral research.

Behavioral sciences research figures prominently in several major Institute-wide initiatives: childhood and adolescent disorders; Alzheimer's disease and other disorders of aging; the Schizophrenia and Long-term Care Plans; homeless severely mentally ill adults and homeless families with children who are at risk of severe emotional disturbance; suicide and suicidal behaviors; minority mental health; rural mental health; and HIV/AIDS programs. In addition, NIMH prevention activities, both research and the precedent-setting D/ART (Depression Awareness Recognition and Treatment) program are components of the behavioral agenda.

The Administration's FY 1991 budget provides funds to increase the research programs of NIMH. Behavioral and psychological research, as an integral part of the Institute's programs, will continue to grow.

PUBLIC ACADEMIC LIAISON

Question. I understand the PAL program is a way to encourage medical researchers to form collaborative relationships with health service providers in the community, and that psychiatry makes great use of this method.

How can nursing and social work take advantage of this program?

Answer. The National Institute of Mental Health, through a variety of mechanisms, has stimulated new interest in controlled scientific research from these two key disciplines. The Public Academic Liaison (PAL) mechanism is ideal for nurses and social workers as well as psychiatrists to develop collaborative research proposals situated in public settings. Therefore, the best way for them to take advantage of this program is by submitting research proposals with PAL linkages.

SUICIDE INITIATIVE

Question. We now know that certain stressful parts of the lifespan place people at a higher risk of suicide, including adolescence, the death of a spouse, entering a nursing home, losing a farm, and so on. A study of adolescents in rural Minnesota communities at the height of the farm crisis showed the rate of suicide attempts to be 15 times higher that the national average. Our concern over suicide led us to direct ADAMHA to devote at least $1 million to suicide prevention demonstrations in FY 1990.

ADAMHA's suicide research plan includes studies on biological risk factors, developmental psychopathology, epidemiology, and more areas. What I don't see, however, is a tie-in with other factors that may contribute to suicide, such as the traumatic life events I mentioned.

Don't these areas deserve your full attention, too?

Answer. The NIMH is currently devoting full attention to all potential risk factors for suicide.

Existing research has identified a number of potential risk factors for suicide, including traumatic life events and transitions. Unfortunately, the quality and reliability of the data on risk factors varies considerably, and often must be considered preliminary in nature. The NIMH Program Announcement inviting Studies of Suicide and Suicidal Behavior therefore encourages systematic research in order to improve our understanding of the etiology of suicide, rigorously characterize high risk groups, and identify potential protective factors. Studies investigating the role of traumatic life events and life transitions are an integral component of the programs in epidemiology and developmental psychopathology.

The Suicide Program Announcement also encourages preventive intervention research focused on high risk groups. The NIMH has also developed a Request for Applications (RFA) for research demonstration projects aimed at the Prevention of Youth Suicide and Suicidal Behavior. This RFA encourages applications to demonstrate the efficacy of (a) interventions for suicide attempters in inpatient, outpatient, or emergency room settings, and (b) community and school based interventions for youth at high risk for suicide. The RFA is expected to be released this spring, with review of applications and funding in late FY 1990.

NIMH currently supports programs such as Depression/Awareness, Recognition, Treatment (D/ART) which are targeted to help such at risk rural populations.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

AIDS

Question. Give us an update on where we are in AIDS research vis-a-vis the neurological and mental effects of the HIV virus. Is NIMH seeking new drugs for the treatment of the brain disorders associated with AIDS?

Answer. Several NIMH supported studies have suggested that HIV-infected individuals show deficits in cognitive and neuropsychological function. Research using an extensive cognitive battery with emphasis on verbal memory and processing speed has indicated that HIV-positive individuals showed statistically significant memory deficits as well as a slowing in the processing of specific types of information compared with HIV-negative individuals.

Other studies have shown that AIDS patients show a markedly worse neuropsychological profile than persons with Lyme disease, another brain infection. Patients' decrements in performance on tests of psychomotor speed and visual-motor skill were found not to be a secondary effect of depression or due to chronic brain infection _per se_, adding to mounting evidence for a subcortical dementia in HIV infection.

In the NIMH intramural research program, approximately 50 percent of the AIDS research is directed toward understanding AIDS Dementia Complex (ADC), including investigation of virus/CNS interactions, cognitive dysfunction and dementia associated with AIDS, and treatment of the HIV effects on the brain. ADC may be caused by direct HIV infection of the brain or by products released by macrophage or the virus. The theory on direct causation in brain has gained rapid acceptance since HIV is similar to other slow viruses that are neurotropic. Data has emerged documenting the clinical pathologic correlates of dementia in AIDS patients where no space occupying tissue or destructive lesion was identified.

NIMH proposes to initiate a new program to develop psychotherapeutic agents from natural sources which may have potential for treatment of HIV infection in the brain. The NIMH will receive plant and animal samples with the potential for yielding such drugs from the National Cancer Institute's Natural Products Screening Program.

NIMH intramural scientists have found markedly increased levels of quinolinic acid in cerebrospinal fluid (CSF) of patients with AIDS dementia. Quinolinic acid, which is normally present only in trace amounts in the brain, is a naturally occurring and potentially neurotoxic byproduct of the metabolic breakdown of tryptophan. CSF levels of this toxic metabolite correlate with dementia ratings of these patients, suggesting that quinolinic acid may play a role in the pathogenesis of AIDS dementia. Since quinolinic acid can be made by macrophages and lymphocytes, which are immune system cells, the investigators postulate that local production of this neurotoxin may be responsible for central nervous system dysfunction underlying AIDS dementia. They also suggest that monitoring CSF levels of quinolinic acid may serve as a marker for AIDS dementia.

HAWAII

Question. What can you tell us about your efforts to assist in the development of Native Hawaiian mental health services research?

Answer. During calendar year 1989, NIMH engaged in several activities to strengthen the capacity of Native Hawaiian mental health professionals to address problems in their own community through research:

In January 1989, Delores L. Parron, Ph.D., Associate Director for Special Populations, met in Honolulu with Mrs. Gladys Brandt, Chairman of the Board of Regents of the University of Hawaii; Albert J. Simone, Ph.D., President of the University of Hawaii; Anthony J. Marsella, Ph.D., Vice-President for Academic Affairs, University of Hawaii; and a group of Native Hawaiian scholars and community leaders to assist them in developing a mental health research agenda and in exploring the various options available within NIMH for funding applications to support these studies including an application for a Minority Mental Health Research Center.

In March, the Institute held the first in a series of workshops on Minority Mental Health Services Research in Honolulu. The purpose of these workshops is to stimulate and develop more minority mental health services research applications. A number of the Native Hawaiian community leaders and scholars participated in the workshop, and a major part of the program focused on mental health services for Native Hawaiians.

In May, Dr. Parron and Lewis Judd, M.D., went to Hawaii and met with Mrs. Gladys Brandt; John Lewin, M.D., State Health Director; Patrick H. De Leon, Ph.D., of Senator Inouye's staff; and other Native Hawaiian community leaders and officials of the University of Hawaii to discuss the development of an application for a Native Hawaiian Mental Health Research Center.

In June, three researchers from Hawaii participated in a technical assistance workshop for minority junior investigators that was held in Annapolis, Maryland. The purpose of this workshop was to provide training in mental health services research methods and grant preparation with the long-range goal of assisting these young researchers in participating in an important program area supported by NIMH. Rosalind Mau, Ph.D., from the Hawaiian Multi-functional Resource Center is participating in the second phase of this program and receiving individual consultation in refining her grant application.

In October, 1989 a Minority Access to Research Careers (MARC) research training grant was awarded to Ruth T. Nishimura, D.S.W., at the University of Hawaii School of Social Work. This successful application was the result of efforts by the Institute in encouraging development of a program to train Native Hawaiians and other minorities for careers in research.

In October, 1989 Freda K. Cheung, Ph.D., and Mr. Ben Z. Locke, Institute Program Staff, went to Honolulu and met with Naleen Andrade, M.D., to provide technical assistance in the preparation of the Native Hawaiian Mental Health Research Center application. Dr. Andrade submitted this application in November 1989.

Dr. Delores Parron sponsored a workshop entitled "Developing an Agenda of Research Needs for AIDS Prevention in Minority Adolescents" in Honolulu on November 17-19, 1989. Three faculty members from the Departments of Psychiatry and Pediatrics of the John A. Burns School of Medicine, University of Hawaii, participated in the workshop. This group is also working on an application that they plan to submit to NIMH for funding to support research on AIDS prevention in Native Hawaiian and other minority populations.

Dr. Parron has taken the leadership role in providing numerous on site and telephone contacts with State, university, and local leaders in pursuing the development of the Native Hawaiian Mental Health Research Center application as well as other activities pertaining to this special population. These extensive efforts have resulted in the submission of a research application that addresses the needs of the Native Hawaiian community. Dr. Parron continues to address the needs of the Native Hawaiian population by encouraging participation of faculty of the University of Hawaii in a research seminar and technical assistance workshop being planned for July, 1990 that is focused on mental health research issues related to HIV infection and AIDS.

PREVENTION

Question. What are you doing in the area of prevention services and research? As you know, the Committee is very concerned about this area. We have also expressed particular concern that new prevention demonstrations be funded, especially in the area of youth suicide. What are your plans?

Answer. The NIMH maintains an active and extensive research program in prevention that spans basic, clinical and applied research. In addition, the Institute supports five prevention intervention research centers at universities, both as centers of excellence for research activity and as a mechanism to stimulate training of researchers for this field.

In addition, the NIMH has developed two Requests for Applications (RFAs) for research demonstration projects in the area of prevention. The first is focused on the prevention of youth suicide and suicidal behaviors in high risk groups. The other is focused on the prevention of serious and chronic antisocial behaviors (conduct disorders) in children and adolescents, behaviors which have also been associated with increased risk of youth suicide. Both RFAs are expected to be released this spring, with review of applications and funding planned for late FY 1990. NIMH will also hold the first national state-of-the-art conference on prevention research in June of this year.

BEHAVIORAL RESEARCH

Question. In last year's report, the Committee mentioned three official reports recommending the NIMH spend more on behavioral and social science research and training. The Committee especially noted that one of these reports attributed recent losses of young NIMH investigators to fewer psychologists and social scientists. Briefly explain what NIMH intends to do about this problem, as outlined in the report recently submitted by NIMH. For example, what new programs aimed at increasing a behavioral and psychological presence at NIMH will be initiated?

Answer. A recent report to Congress and two reports by the National Academy of Sciences point to the immediate need to enhance the role of the behavioral and social sciences in the study of mental illness. These reports complement the efforts of NIMH to strengthen its programs in these areas. The National Academy of Sciences' report notes that federal support for the behavioral and social sciences was 25 percent lower in 1987, in constant dollars, than support provided in 1972. Despite the declining Federal role, NIMH increased its support for research in these areas from $26.1 million in FY 1984 to $53.8 million in FY 1989.

NIMH has many ongoing programs and future plans to meet the need expressed by Congress, and to take advantage of the scientific opportunities in the behavioral and social sciences. In January of 1989, the NIMH Extramural Science Advisory Board undertook an assessment of behavioral sciences research supported by the Institute and attested to the importance of strengthening the Institute's basic research programs in cognitive science; behavioral genetics; biopsychology, including animal models; personality, emotional and social processes; and longitudinal studies of behavioral process. In addition to current programs there are emerging opportunities for the behavioral and social sciences in recently implemented major NIMH initiatives; for example, in schizophrenia, child and adolescent mental health, AIDS prevention, and many other areas.

To facilitate an enhanced presence of the behavioral and social sciences in these major initiatives, NIMH is restructuring its Division of Basic Sciences. The new Division will be called the "Division of Basic Brain and Behavioral Sciences". This new organization will ensure that behavioral concerns will be an integral part of the focus in future research and will broaden the scope of behavioral science research at NIMH. This newly structured Division will not only enhance our efforts in the behavioral sciences, but it will also foster the multidisciplinary research needed to fully understand the complexities of human behavior.

To ensure the success of these programs, NIMH intends to implement recommendations contained in the ADAMHA report on the shortage of young principal investigators, particularly in the behavioral and social sciences. These recommendations call for the NIMH to continue to educate the scientific and academic communities about NIMH-supported research, career development, and research training opportunities. NIMH will also continue the recently implemented program to provide postdoctoral fellowships for students in combined M.D./Ph.D. programs to increase the number of researchers. To increase awareness about the problems and importance of the behavioral and social sciences NIMH will work with other government agencies involved in science education. The Institute will explore areas in which it can cooperate with the private sector.

SEVERELY MENTALLY ILL

Question. What is the National Research Strategy to Improve the Care of the Long-Term Severely Mentally Ill and what is its status?

Answer. This National Strategy represents an effort to extend the Institute's National Plan for Schizophrenia Research into the area of services research to find more effective ways of delivering care for the people who have these serious, persistent, disabling illnesses. One of the panels in the National Plan for Schizophrenia Research examined Treatment, Services, and Environmental Factors, and its report was a useful first step in examining research that is needed to improve the delivery of mental health services.

When he became NIMH Director in January 1988, Dr. Judd recognized that little was known about the best way to organize and finance effective methods of providing care in the community. A new National Strategy was needed to examine the serious knowledge gaps and recommend ways to meet them over the next decade. Three panels began meeting in May, 1989, in the areas of Clinical Services Research, Service Systems Research, and Research Resources. These were headed by distinguished researchers from three of the five new Centers for Research on Organization and Financing of Services for the Seriously Mentally Ill, which met periodically through 1989. During the course of the review, the panel received input from a range of consultants representing consumers, families, public and private systems of care, and researchers from this country and abroad.

The draft panel reports will be circulated for comment in February and March, 1990, and the NIMH hopes to publish them in early summer. At the same time, the Institute is preparing an overall National Strategy based on the three panel reports which will be ready for review by the National Advisory Council in September, 1990. This process has been a thoughtful, comprehensive review of the issues facing delivery of care and will provide a sound guide for future research as well as for mechanisms to assure that research findings will be applied by policy makers and administrators.

PUBLIC ACADEMIC LIAISON (PAL) PROGRAM

Question. Last year we heard testimony about a Public Academic Liaison Program to encourage academic researchers to form collaborative working relationships with public mental health service settings? How is this program progressing? Describe some of its current activities.

Answer. NIMH has developed the Public Academic Liaison (PAL) initiative to address parallel problems caused by the separation of the academic research environment from the public mental health system and its patients. The program seeks to increase the interaction between the public sector clinical staff, who have years of experience treating seriously ill patients, and the university-based researchers. The corresponding goal, is to increase the rate of adoption of advances made by researchers in public mental health treatment centers. It is believed that the program can stimulate both: research hypotheses responsive to the clinical needs of chronically patients, and more targeted efforts to improve clinical care through formal trials of alternative treatment programs.

The Public Academic Liaison (PAL) initiative is rapidly expanding to encompass all the programs of the National Institute of Mental Health including research project grants, research demonstration projects, research training, and especially service system research.

Current activities include two requests for applications (RFAs) focused on: (1) developing collaborative PAL relationships to stimulate research proposals on serious mental disorders, and (2) training in public settings. In addition, NIMH sponsors a yearly national meeting focused on issues relating to PAL.

RURAL

Question. The committee is very concerned about the growing reports of mental disorders in rural areas of America, including substance abuse and depression, which are in turn reflected in a growing suicide rate. Although research and data on rural mental health have unfortunately been scant, the information that does exist is disturbing. A 1986 study of adolescents in three communities in rural Minnesota, for example, showed the rate of suicide attempts to be 15 times higher than the national average.

The Committee further requested a full report on the desirability of establishing an office of Rural Mental Health at NIMH. Please tell me your specific plans with respect to this office.

Answer. The Office of Rural Mental Health Research (ORMHR) has been established at NIMH by expanding the purview of the Associate Director for Special Populations, to include persons living in rural areas. Efforts are underway to recruit and hire a full-time Director for this office and appropriate support staff. Until the Director (ORMHR) is in place, Delores Parron Ph.D., Associate Director for Special Populations will function as Acting Director.

The ORMHR has provided leadership in developing a Research Announcement "Research on Mental Disorders in Rural Populations" which is intended to stimulate research on mental disorders as they occur in Americans living in rural areas. The announcement encourages three types of applications, 1) traditional research grant applications for specific studies (regular research grants (R01), small grants (R03), and First Independent Research Support and Transition (FIRST) Awards (R29); 2) research demonstration grants (R18); and 3) applications to establish a research center (P50). In addition, all new Requests for Applications (RFAs) and Research Announcements (RAs) issued by NIMH research program divisions incorporate the following notice to applicants: "Special encouragement is given to applicants for grants under this announcement to undertake studies on issues related to rural mental health or persons living in rural areas."

ORMHR has initiated liaison with the Office of Rural Health Policy as a step toward collaboration and coordination of activities.

Inquiries related to rural mental health concerns are being received and processed by ORMHR as appropriate.

ORMHR will coordinate technical assistance activities related to the research announcement--Research on Mental Disorders in Rural Populations.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

NIDA AIDS OUTREACH DEMOS

Question. The ADAMHA budget justification suggests that there is a $15 million increase for the agency for AIDS. However, the budget proposal includes a reduction in the NIDA drug user outreach and demonstration program, which has proven successful in contacting users on the street, helping them to change behavior, and getting them into treatment. What is the agency's justification for cutting this program by over $20.1 million? I am concerned about this proposal to cut funding for a program designed to teach us how to serve the most vulnerable AIDS population, the IV drug user. At a time when prevention of AIDS transmission among this population must be one of our central goals, how can the agency defend a program that is the only one of its kind -- a research demonstration program that is beginning to provide data and develop models of quality prevention efforts?

Answer. NIDA is conducting the final phase of a national demonstration research effort designed to implement and evaluate different outreach, AIDS education, and behavioral change intervention methods targeted to intravenous drug users and their sexual partners in the community setting. These demonstration research projects have yielded important results. They have shown that many intravenous drug abusers have never been in treatment and that many engage in high risk needle sharing and sexual behaviors. Many intravenous drug abusers contacted by the outreach workers were found to be willing to reduce or eliminate high risk behaviors and many were willing to consider drug abuse treatment. However, treatment was not always available and that which was available was often inadequate. The outreach studies also showed that the intravenous use of cocaine is a serious problem and that injection linked HIV infection is not limited to persons who abuse heroin and other opiates. In fact, higher HIV seropositive rates are found for IV cocaine users than IV heroin users in several cities.

NIDA's mission, as a research Institute, is to identify knowledge gaps and move to fill them. The Outreach Demonstration Projects fulfilled the purpose of identifying areas where further research is needed. The limited timeframe for demonstration projects enables ADAMHA to conduct research which will concentrate on development of better methods for encouraging drug abusers into treatment as well as better methods for treating drug abuse. This is a logical progression from the initial community outreach studies and builds on that foundation.

While NIDA will no longer support the current demonstration projects past their approved project periods, the States in which they are located may use funds from the expanded drug abuse portion of the ADMS block grant to continue these programs. It should also be pointed out that each of these outreach projects is preparing a manual explaining how to establish and run similar programs. ADAMHA's focus, then, would be to move on to other important program areas.

Question. Mental health concerns are growing in importance in the context of the AIDS epidemic. We are increasingly hearing reports about high rates of extreme depression, suicide ideation and even actual suicides. It is clear from some of the initial data that disorders such as depression may have a direct adverse impact on the patient's immune functioning and thereby hasten the onset of frank AIDS. In 1988, Congress authorized the creation of a mental health research demonstration program to assess the efficacy of mental health interventions for persons experiencing adverse reactions to an HIV test. While ADAMHA has convened an expert group to develop a model protocol for this program, the agency has not requested funds for administration of this activity and has indicated that HRSA is expected to take a lead role in this area. How can the agency neglect a role which seems so vital to its mission in the area of research, national leadership, and development of model programs?

Answer. P.L. 100-607 stipulates that the Secretary, acting through the Director of NIMH, may provide technical assistance and administrative support to grantees under this provision of the legislation. NIMH has provided funds for these efforts in FY 1989; has plans to provide funds for technical assistance efforts in FY 1990; and has requested funds for FY 1991.

In FY 1989, NIMH developed an HIV-related counseling strategy following a meeting of research and clinical experts in HIV mental health counseling. This expert group recommended that counseling programs should adopt a broad, integrated approach that focuses on mental health needs, but takes into account the interrelationship of the individual's medical, social, and psychological needs. They advised that mental health counseling services should be integrated into ongoing systems of care for HIV disease to enhance treatment, provide continuity of care, and foster acceptance of mental health counseling for HIV-infected individuals. They felt that counseling programs should be based at, or have relationships with, entities providing comprehensive health services to individuals with HIV infection.

HRSA currently supports such comprehensive programs through the AIDS Service Demonstration Projects. In response to the HOPE legislation, NIMH and HRSA are working together in FY 1990 to evaluate existing HRSA service programs which include a mental health counseling component. Such an evaluation will review ongoing mental health counseling and effective strategies and will identify existing gaps and needs.

NIMH continues to take the lead responsibility to stimulate studies to identify successful mental health counseling approaches for individuals who are infected and affected by HIV and AIDS. An NIMH Prevention Workgroup Meeting in March 1990 will consider research data regarding the role of pre- and post-HIV antibody test counseling in preventing the further spread of HIV infection.

In the NIMH Health Care Worker Training Program, health and mental health care providers are being trained in pre- and post-test counseling techniques as well as the recognition and treatment of psychosocial and neuropsychiatric consequences of HIV infection and AIDS. AIDS mental health training is currently being integrated into the ongoing health care training being provided through the HRSA AIDS Education and Training Centers.

In FY 91, NIMH will continue to work with HRSA and their grantees. NIMH and HRSA will convene a meeting of staff in projects that are providing mental health counseling to discuss ongoing mental health counseling strategies. NIMH will provide technical assistance necessary to facilitate the integration of these mental health and counseling services into ongoing health care programs for this population.

AIDS PREVENTION

Question. While ADAMHA assures Congress that it is one of its central priorities, it is spending less than half of its AIDS research dollars in this area. Of the 15 million dollar increase the Agency has asked for, only 31 percent is going to the category of activity devoted to prevention. How can ADAMHA assure me that it is doing everything to address the prevention agenda, that there are not major unmet needs, and that its spending priorities are not out of balance?

Answer. NIMH has been increasing emphasis on AIDS prevention research. Currently, approximately 56 percent of the NIMH AIDS basic science research effort focuses on behavioral research. Most of these projects are related to the development of AIDS prevention strategies.

NIMH shares the prevention mission with CDC and HRSA. In March 1990, NIMH is co-sponsoring a meeting on prevention with NIDA, CDC, and HRSA. Representatives from OSAP and ODPHP will also attend. The purpose of the meeting is to review AIDS prevention efforts in research, training, and services. Gaps in prevention activities will be identified and strategies will be recommended for facilitating the dissemination of AIDS prevention research findings to clinical and community settings. Collaborative approaches will explore more effective linkage of AIDS research, training, and services.

Several initiatives are underway to expand AIDS prevention research efforts, including 1) a cooperative agreement for a coordinated multi-site, multi-population AIDS prevention trial and 2) a meeting of NIMH-supported AIDS prevention researchers to recommend research priorities for AIDS prevention.

Prevention is a high priority at NIDA. Looking at the FY 1991 AIDS budget tables, it would appear that NIDA is proposing to spend $28,915,000 (or only 21 percent of its request) on the category Risk Assessment and Prevention. Within the Basic Science Research category, however, an additional $82,371,000 is budgeted for Behavioral Research on the Prevention of High-Risk Behaviors. When these amounts are combined, the total budgeted for FY 1991 is $111,286,000, or 80 percent of NIDA's total request.

Almost 90 percent of NIAAA's FY 1991 requested budget increase for HIV/AIDS is research targeted to prevention. $878,000 of the requested $992,000 increase is identified specifically for research on mechanisms of behavior, behavior change, and prevention of high-risk behaviors.

QUESTIONS SUBMITTED BY SENATOR HARRY REID

OFFICE FOR TREATMENT IMPROVEMENT

Question. Last year, ADAMHA created a new Office for Treatment Improvement.

What do you hope to accomplish through this office, and what will this office do to evaluate different treatments, disseminate that information, and provide technical assistance to treatment programs to organizations that are trying to improve their programs?

Answer. OTI's mission is to improve the overall quality of drug treatment services nationwide. During its initial year in operation, OTI will use its $72 million in discretionary funds for several programs. OTI also provided $40 million in Waiting List Reduction Grants to help alleviate the national shortage of drug treatment slots and services.

OTI provides comprehensive financial assistance to selected cities to improve the overall quality of drug abuse treatment services. Special emphasis will be placed on helping these cities develop or strengthen central intake and referral capabilities, improve treatment programs, expand post-treatment services and follow-up, and augment program evaluation.

Funds are also used to support treatment improvement efforts of programs serving populations with critical needs, with a focus on ethnic minorities, adolescents, and residents of public housing. OTI also strengthens drug abuse coordination with State and local correction systems including selected funding of projects that encourage individuals convicted of drug related crimes to seek treatment in lieu of incarceration, augmenting drug treatment services in prisons and correctional facilities, or strengthening management of drug treatment for released individuals by parole officials.

In addition, OTI will work with NIDA to identify information from NIDA treatment efficacy research that is ready for dissemination to State and local drug treatment administrators and clinicians. OTI will sponsor workshops, conferences, and prepare "hands-on" written material to assist the treatment community in adopting proven treatment modalities identified through NIDA basic, applied and clinical research.

Question. By what methods will OTI evaluate treatments to determine their effectiveness?

Answer. All programs OTI funds will have strong evaluation components, thereby enabling OTI to disseminate the results of these demonstration activities. Evaluation methodologies will be established as part of each program as it is developed.

OTI is working with State drug abuse authorities to install a voluntary system of annual States Substance Abuse Service Planning. Through this process, OTI will encourage States to improve the quality and accountability of the public treatment system by strengthening State planning and management. OTI will conduct State management reviews and provide technical assistance to States to help them improve administration of federal and State drug abuse activities.

Question. How will this office help smaller programs, such as the ones in my home State of Iowa, get up to speed on treatments of proven effectiveness?

Answer. During FY 1990, OTI will sponsor a series of six technical assistance conferences for State and selected local drug abuse treatment officials. This conference will focus on drug treatment for the homeless, special treatment services for women, assessing needs for drug abuse treatment services, performance criteria for assessing treatment effectiveness, coordinating drug abuse treatment with other needed medical, social, educational and vocational services at the State and local levels, and improving coordination between community drug treatment and the correctional system.

OTI will establish a national consultant exchange program through which State and local treatment providers may obtain the services of specialists and clinicians with particular expertise to help design and improve their treatment programs. Through this consultant program, the Treatment Improvement Exchange, it is envisioned that approximately 300 such experts will be identified and made available with federal funds during FY 1990 and FY 1991. The effectiveness of this exchange program will be evaluated with intensive follow-up to determine the degree to which the experts were helpful to those seeking assistance and the nature of change or improvement in treatment efforts that resulted from on-site technical assistance.

OTI plans to develop, through consensus efforts, treatment standards and guidelines for use by State and local programs. A high priority during FY 1990 will be the development and dissemination of guidelines for measuring the effectiveness of treatment programs, or program "performance criteria." OTI will also develop standard definitions for use by the field, such as what comprises "comprehensive treatment services."

INTERGOVERNMENTAL COORDINATION TO FIGHT DRUGS

Question. The President's drug control plans call for increasing Federal, State, and local coordination, and for making treatment programs more accountable.

What steps have been taken to implement the recommendation from the President's National Drug Control Strategy for greater State, local, and individual treatment program accountability for effectiveness?

Answer. ADAMHA has taken a number of actions to effect treatment accountability by Federal, State, and local governments in the administration of Alcohol, Drug Abuse, and Mental Health services delivery programs. These actions have emphasized cooperation between the different organizational levels and between different components dealing with the ADM problems, such as Justice and Education Departments. They go beyond the Governor's assurance that a State will meet the requirements and restrictions of the law, the holding of public hearings on the intended use of the funds, and yearly audits for both programmatic and fiscal compliance.

For example, ADAMHA oversees program accountability through a compliance review process. Under this process selected States are subjected to an on-site review for compliance with the mandated requirements of the law. ADAMHA staff is also designing an on-site Management Review process to assess over-all State performance and to determine State-specific technical assistance needs.

Future activities to improve coordination and treatment program accountability include the holding of technical assistance workshops on Needs Assessment, Coordination of Services, Criminal Justice Coordination, and Outcome Measurement. ADAMHA will obtain input from National organizations and State and local ADM Directors on both the design and execution of all future activities.

ADAMHA staff has been working with the National Association of State Alcohol and Drug Abuse Directors and several State Directors to develop a voluntary State Drug Treatment Plan that will include coordination and outcome measurement components. This voluntary activity underscores the readiness of ADM service providers to increase coordination and program accountability.

Lastly, two ADAMHA programs have specific focus on coordination of community services to enhance intervention effectiveness. The Office for Substance Abuse Prevention (OSAP), through its Community Partnership Demonstration Program, provides long-term, multidisciplinary resources to assist communities in developing comprehensive, collaborative, and systematic approaches which emphasize local community involvement, systems, and environmental changes reflecting that community's values and institutions. OSAP's Pregnant Women and Infants program is designed to develop innovative, community-based models of education, prevention, and/or treatment, for substance abusing women and their infants. These demonstration grant programs are designed to promote the coordinated participation of multiple organizations in the delivery of comprehensive services for substance using pregnant and postpartum women and their infants.

Question. What are the States doing to implement the President's call for improved coordination between treatment facilities and social, employment, and health agencies in order to assist drug-dependent people with the range of services they need; and what is ADAMHA doing to assist States in this effort?

Answer. There is an increased recognition among State drug abuse treatment officials that drug-dependent individuals require a variety of services and supports in addition to drug treatment services, if the effectiveness of drug treatment is to be improved. Although ADAMHA does not now have systematic and comprehensive information about what all the States are currently doing to increase the coordination of these services, it has initiated several activities to help States strengthen the coordination of needed activities.

For example, in early 1989, ADAMHA co-sponsored, along with the Departments of Education, Justice, three Anti-Drug Abuse Seminars for State officials responsible for drug abuse education and justice programs. These seminars involved hundreds of State officials and encouraged the strengthening of coordination in States and localities. Numerous participants credited these seminars with fostering greater interaction and coordination.

Later in 1989, ADAMHA initiated a small study to review the state-of-the-art of coordination for alcohol, drug abuse, and mental health services. An early draft of this review will be the topic of a one-day meeting with about six State officials in the spring of 1990, to be followed by a second small meeting. ADAMHA will soon announce a national technical assistance conference, to be held in the spring of 1991, to help State officials focus on techniques to improve the coordination of drug treatment and related services and supports.

With the creation of the Office for Treatment Improvement (OTI), ADAMHA will further foster improved coordination through a voluntary State planning process. Among other things, States will be asked to describe their current efforts to coordinate needed services and to indicate the need for technical assistance. Based on these findings, OTI will provide extensive on-site management reviews and a national Treatment Improvement Exchange that will provide individuals with relevant experience and expertise to help States requesting assistance.

OTI is supporting initiatives to mainstream drug treatment into the health care system, to improve drug treatment for those incarcerated in jails and prisons, to increase the availability of group homes and other kinds of supported housing, and to strengthen the development of a variety of coordinated services and systems needed to provide and enhance the efficacy of drug treatment in selected target cities.

OTI will also fund treatment improvement demonstrations in approximately 6 urban jurisdictions this year. Total funds available for this program are approximately $28 million for FY 1990 and an estimated $32 million in FY 1991. The primary goal of this program is to implement overall systemic improvements in metropolitan settings.

OSAP initiated, in FY 1990, with funds provided by P.L. 101-164 and P.L. 101-166, the community prevention (partnership) program is designed to stimulate the formation of local coalitions, consortiums and partnerships for the purpose of developing comprehensive, multi-disciplinary drug abuse prevention systems. This program promotes sound, long-term prevention systems by creating a forum through which local interests, including parents, youth, representatives from business and industry, religious institutions, civic groups, health care agencies, local governments, and other organizations can work together to implement community-wide alcohol and other drug abuse prevention and treatment initiatives.

IV DRUG TREATMENT CAPACITY

Question. The 1988 Anti-Drug Abuse Act requires States to respond to reports from local drug abuse treatment programs that have reached 90 percent of capacity with assistance to ensure treatment services within seven days for any IV drug abuser who requests treatment.

How are States implementing this requirement?

Answer. All States were required to provide an assurance in their application for FY 1989 funding under the ADMS Block Grant that the State would implement this provision. Each State has provided that certification.

ADAMHA has provided technical assistance to the States on all aspects of the block grant legislative requirements including discussion on the importance of this particular provision. Meetings were held with a variety of State officials during 1989 at the following locations: Washington, D.C., Alexandria, Virginia, San Antonio, San Francisco, Indianapolis, Des Moines, and St. Louis. ADAMHA also discussed this matter with State representatives and staff from the National Association of State Alcohol and Drug Abuse Directors, the National Association of State Mental Health Program Directors, and the Alcohol and Drug Problems Association of North America.

ADAMHA provided funding totalling $100 million in FY 1989 and FY 1990 to implement the Drug Abuse Treatment Waiting List Reduction Program to enhance State capacity to provide treatment services to high priority populations. Virtually all of the funded entities served community-based programs with high percentage utilization rates, often to provide services to IV drug abusers within the seven-day period referred to in this provision.

Finally, the State is statutorily required to report annually to the Secretary on how the State has carried out the provisions of the Block Grant legislation. The annual report covering activities of the State for FY 1989 is to be submitted by States within the next several months. Specific information on how each State has implemented this provision will be available approximately July 1990.

SUBSTANCE ABUSE COUNSELORS

Question. We vastly increased funding in FY 1990 for training substance abuse counselors. How many substance abuse counselors and other alcohol and drug abuse health professionals will be trained by OSAP programs in FY 1991?

Answer. A significant amount of new funds was provided in FY 1990 for the training program, with the largest single block of these funds designated for substance abuse counselor training. Under this initiative, approximately 20 contracts will be awarded to various training and educational organizations to provide training for entry level substance abuse counselors in the first year, and advanced training for practicing counselors in the second and third year. In FY 1991, OSAP expects to support the training of 3,500 new counselors. Another 3,500 existing counselors will benefit from brief skills-enhancement seminars.

Other health professionals such as physicians and nurses are being trained through a variety of OSAP National Training System cooperative efforts. For example, one effort will pilot and provide training materials for all the primary care providers in the over 600 community health centers and migrant health centers across the country. Another cooperative effort is with Brown University for the development and piloting of physician continuing medical education module and, through the 600 physician members of the American Society of Addiction Medicine (ASAM), the training of physician trainers for this effort. Dissemination of these modules will be made to all AMA members. OSAP will sponsor training for over 6,000 physicians, nurses, social workers, and other primary care providers in FY 1991.

While this adds to over 13,000 OSAP sponsored trainees, it actually will be greater when considering the thousands to be reached through dissemination of training materials upon request.

HOMELESS

Question. What is the planned FY 1991 level of support for programs that serve the homeless? What support will be given to the homeless in rural areas who are mentally ill or substance abusers?

Answer. The FY 1991 President's Budget requests $72,069,000 for Homeless programs throughout ADAMHA. That funding is split between the McKinney Programs (Mental Health Services to the Homeless Block Grant, and Mental Health and NIAAA Homeless Demonstrations) and the homeless demonstrations in the non-McKinney Community Support Program.

In NIAAA, the Alcohol and Drug Homeless Research Demonstration program will provide 18 awards at $9,498,000. The target population of this program primarily includes all homeless persons and those at imminent risk of becoming homeless who have alcohol and/or other drug problems. These research demonstration projects are intended for location in urban centers with populations greater than 250 thousand persons or in less populated areas where the applicant for an award can demonstrate evidence of sufficient members of the target population to permit a rigorous evaluation design.

ADAMHA plans $33,703,000 for the MHSH Block Grant Program which provides funds to all States, the District of Columbia, and the Territories for mental health services for the homeless. These funds are allotted according to a formula, based on the proportion of a Sates' population in urbanized areas relative to the total national population in urbanized areas. The President's budget provides a 21 percent increase for this program over FY 1990.

Mental Health Services Demonstrations Projects amounting to $6,006,000 are also planned. These projects are intended to develop and evaluate comprehensive service systems for homeless mentally ill individuals. In FY 1991, NIMH anticipates awarding approximately 24 grants.

In addition to the McKinney programs described above, NIMH administers the Community Support Program. We plan to award $22,862,000 in grants that promote the development of effective, comprehensive, community-based systems of care for adults with severe and persistent mental illness. State Service System Improvement Projects encourage States and communities to give greater priority to the needs of those who are homeless or living in unstable housing situations.

Additional to the programs described above, NIMH conducts an on-going research program on homelessness and its relationship to mental illness. The purpose of this initiative is to accelerate the development of knowledge that can contribute to more effective delivery of mental health services to homeless adults and homeless families and children. In FY 1991, NIMH will make third year continuation awards to 10 research and research demonstration projects and second year continuation awards to 6-8 grantees.

One of these FY 1991 third year continuation awards will support research focused on rural homelessness. This grant "Rural Homelessness in Ohio: A Five-Year Study" will identify changes in the size and characteristics of rural homelessness; develop additional knowledge about the causes of rural homelessness, estimate the prevalence of mental illness among the rural homeless in Ohio; and study service access and utilization among the homeless mentally ill population.

To encourage expanded research in the area of rural homelessness, the NIMH will issue a new research announcement in FY 1990 on the mental health needs of rural persons with special emphasis on the mental health needs of the rural homeless population. This new announcement will be in addition to the current NIMH homeless research announcement which also encourages studies of the mental health needs of rural homeless persons.

PAYMENTS DON'T FOLLOW PATIENTS

Question. What proportion of federal dollars spent on mental health treatment is spent on inpatient versus outpatient?

Answer. Data from the NIMH national reporting program indicate that in 1986 organizations that provide mental health care received an estimated $4.9 billion in Federal funds. Approximately $4.1 billion (84 percent) was received by organizations that primarily offer inpatient or residential care (e.g., State hospitals, non-Federal general hospitals). The balance, approximately $0.8 billion (16 percent), was received by organizations that primarily offer ambulatory care (e.g., psychiatric outpatient clinics, multiservice mental health organizations).

BEHAVIORAL RESEARCH

Question. Dr. Goodwin, your budget justification notes the major issues of concern to the House and Senate Subcommittees, and is supposed to outline ADAMHA's response to those concerns.

Yet I note your budget justification ignores all the Senate report language on behavioral research. That language cites reports issued in the last year by the National Academy of Sciences and others recommending that NIMH spend more on behavioral and social science research and training. For example, National Academy of Sciences reports call on ADAMHA to devote $80,000,000 more per year to behavioral and social science, which is ripe for major breakthroughs, and to commit significant additional funds to study psychological, behavioral, and social interventions aimed at stemming the AIDS epidemic.

The Committee also directed the Director of NIMH to report back to us on plans to increase the behavioral and psychologic presence at NIMH.

What can you report?

Answer. NIMH continues to meet its responsibility as the focal point for Federal Government social and behavioral research in the mental illnesses. NIMH is finalizing a thorough report on "Behavioral and Social Science Research at NIMH" in response to the request contained in the FY 1990 Appropriations Committee Bill Report which will be available shortly.

Whatever their fundamental causes, mental illnesses manifest themselves as disorders of behavior. The growth of the basic brain sciences in the Institute's research program is only part of the coordinated effort to address mental illnesses. In fact, from FY 1984 through FY 1989, funding for research with a primary behavioral or social science focus has increased 106 percent. Major NIMH research programs have been initiated anticipating the findings of the National Academy of Sciences and other studies and more are being implemented or developed to respond to external and internal recommendations.

NIMH is the focal point within the Public Health Service for AIDS research both on behavior and its psychological and psychosocial determinants, and on primary prevention to modify high risk sexual behaviors. The Institute has undertaken a series of activities to foster programs of basic and applied social and behavioral research relevant to HIV infection and AIDS. In FY 1989, slightly more than half of the grants in the NIMH AIDS program were behavioral research projects. The FY 1990 and FY 1991 NIMH AIDS budgets continue this level of support for behavioral research.

Behavioral sciences research figures prominently in several major Institute-wide initiatives: childhood and adolescent disorders; Alzheimer's disease and other disorders of aging; the Schizophrenia and Long-term Care Plans; homeless severely mentally ill adults and homeless families with children who are at risk of severe emotional disturbance; suicide and suicidal behaviors; minority mental health; rural mental health; and HIV/AIDS programs. In addition, NIMH prevention activities, both research and the precedent-setting D/ART (Depression Awareness Recognition and Treatment) program are components of the behavioral agenda.

The Administration's FY 1991 budget provides funds to increase the research programs of NIMH. Behavioral and psychological research, as an integral part of the Institute's programs, will continue to grow.

PUBLIC ACADEMIC LIAISON

Question. I understand the PAL program is a way to encourage medical researchers to form collaborative relationships with health service providers in the community, and that psychiatry makes great use of this method.

How can nursing and social work take advantage of this program?

Answer. The National Institute of Mental Health, through a variety of mechanisms, has stimulated new interest in controlled scientific research from these two key disciplines. The Public Academic Liaison (PAL) mechanism is ideal for nurses and social workers as well as psychiatrists to develop collaborative research proposals situated in public settings. Therefore, the best way for them to take advantage of this program is by submitting research proposals with PAL linkages.

SUICIDE INITIATIVE

Question. We now know that certain stressful parts of the lifespan place people at a higher risk of suicide, including adolescence, the death of a spouse, entering a nursing home, losing a farm, and so on. A study of adolescents in rural Minnesota communities at the height of the farm crisis showed the rate of suicide attempts to be 15 times higher that the national average. Our concern over suicide led us to direct ADAMHA to devote at least $1 million to suicide prevention demonstrations in FY 1990.

ADAMHA's suicide research plan includes studies on biological risk factors, developmental psychopathology, epidemiology, and more areas. What I don't see, however, is a tie-in with other factors that may contribute to suicide, such as the traumatic life events I mentioned.

Don't these areas deserve your full attention, too?

Answer. The NIMH is currently devoting full attention to all potential risk factors for suicide.

Existing research has identified a number of potential risk factors for suicide, including traumatic life events and transitions. Unfortunately, the quality and reliability of the data on risk factors varies considerably, and often must be considered preliminary in nature. The NIMH Program Announcement inviting Studies of Suicide and Suicidal Behavior therefore encourages systematic research in order to improve our understanding of the etiology of suicide, rigorously characterize high risk groups, and identify potential protective factors. Studies investigating the role of traumatic life events and life transitions are an integral component of the programs in epidemiology and developmental psychopathology.

The Suicide Program Announcement also encourages preventive intervention research focused on high risk groups. The NIMH has also developed a Request for Applications (RFA) for research demonstration projects aimed at the Prevention of Youth Suicide and Suicidal Behavior. This RFA encourages applications to demonstrate the efficacy of (a) interventions for suicide attempters in inpatient, outpatient, or emergency room settings, and (b) community and school based interventions for youth at high risk for suicide. The RFA is expected to be released this spring, with review of applications and funding in late FY 1990.

NIMH currently supports programs such as Depression/Awareness, Recognition, Treatment (D/ART) which are targeted to help such at risk rural populations.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

MENTAL HEALTH CONSUMER SELF-HELP ORGANIZATIONS

Question. Has the NIMH supported research and demonstration projects which assess, promote or establish self-help groups for present and former mental health patients?

Answer. Yes, the NIMH Community Support Program is currently supporting 14 projects to demonstrate and evaluate a variety of approaches to promote the development of self-help groups for present and former mental health patients.

In terms of research projects, NIMH has funded two recent grants that deal with self-help groups for present and former mental patients. One of these, at the University of Pittsburgh, is following a cohort of individuals discharged from public mental hospitals to determine what characteristics promote successful use of self-help services, what factors lead to drop-out, and what factors promote more successful outcome in those who do use self-help groups or other services. This project is using random assignment to test the outcome of self-help and peer support groups compared to traditional services. Another grant, at the University of Illinois, has been examining the impact of participation in Project GROW, a network of consumer-led self-help groups, on individual outcome, social networks, and friendship patterns; it is also examining the development of the organization over time. In this project, comparisons are being made to matched controls in hospital settings.

In addition the NIMH funded a new National Center in fiscal year 1989, which has its major aims conducting a research program on self-help services and disseminating knowledge to consumers about effective self-help services. It has a special focus on severe disorders and on minority populations.

Question. Does the FY 1991 budget assume funding for demonstration projects in the area of consumer-run self-help organizations?

Answer. In FY 1991, the NIMH Community Support Program will support projects to demonstrate and evaluate a variety of approaches to promote the development of self-help groups for present and former mental health patients.

Question. What plans does the NIMH have to fund a national technical assistance center for mental health consumers?

Answer. In fiscal year 1989, NIMH funded a new National Center for Research and Knowledge Dissemination on Consumer-led Self-Help Services. After open competition and peer review, the grant was awarded to the University of Michigan, which has established a new center to conduct research in collaboration with local consumer-led groups, including the local chapter of the National Depressive and Manic-Depressive Association, and to provide technical assistance and knowledge dissemination to consumer, family, and professional groups on self-help services. That center will establish a National Advisory Board to offer guidance to these research and dissemination activities. The research questions it is studying include (a) how self-help groups can develop more effective programs, (b) how persons with severe mental disorders can make effective use of self-help groups, and (c) how self-help services can be integrated and coordinated with professional services.

In addition, as I have mentioned, both research and research demonstration funds are being used to fund studies of self-help services, for example, in a two-year follow-up of individuals with serious disorders like Schizophrenia discharged from a public mental hospital.

To consider the state-of-the-art in this area, NIMH conducted a workshop on self-help services in March, 1990, with the active participation of researchers and consumer leaders active in their own self-help services. One outcome of that meeting was agreement to continue the sessions by holding another meeting later in the year to focus on more specific gaps in knowledge. For example, it is clear that not enough is known about what kind of clients benefit from participation in self-help services, what variations in self-help services might be most effective for different aims, and what models of sponsoring and supporting self-help services work best in sustaining these efforts in different communities. There was good agreement that the promising developments in this area of services warrant further study, and NIMH is committed to encouraging that research as a full and mutual collaboration of researchers and consumers.

Once more knowledge is developed about the fundamental questions, NIMH will also consider whether additional technical assistance efforts are needed, and what form these might best take.

SEQUESTRATION

Question. How has the partial sequester of funds in FY 1990 affected the level of mental health research activity? What specific programs and activities did you have to reduce or curtail?

Answer. The total NIMH sequestered amount is $4,623,000 of which $3,752,000 is for Non-AIDS and $871,000 for AIDS.

The Non-AIDS budget reduces the number of new/competing research project grants (RPGs) by 15 from 351 to 336. The same reduction of 10 percent from full Council recommended amounts applies at both levels. The continuation RPGs are reduced further downward from 8 percent to 10 percent. The number of full time trainee positions were reduced by 50, from 1,100 to 1,050 in research training. The intramural research program and research management and support activities are reduced by less than one-percent.

This reduction affects all areas of the mental health research activities and programs.

The AIDS budget maintained the same number of RPGs but the cost of each grant is being reduced further, from 3 percent to 5 percent for continuations and 8.5 percent for the new/competing. The one new cooperative agreement was reduced by 15 percent. The number of full time trainee positions were reduced by 5 from 130 to 125 in research training. The research management and support activity was reduced by less than 1 percent.

This reduction affects all functions of the mental health research activities on AIDS.

DECADE OF THE BRAIN

Question. Recently, the NIMH prepared a major Decade of the Brain report to Congress which described programs thus far, and the many opportunities which now exist in NIMH neuroscience research. Please briefly describe the major programs which are in place or planned to begin implementation of the Decade of the Brain.

Answer. The Decade of the Brain activities currently in place include:

1. Five research centers are currently funded for the Neuroscience of Mental Disorders at Maryland Psychiatric Institute; University of California, Irvine; University of Colorado, Denver; University of Pittsburgh; and Yale University.

2. In the area of molecular genetics, the "Tissue Bank Program" currently funds nine Diagnostic Centers for Psychiatric Linkage to gather clinical information and blood samples from families with multiple affected members (e.g. at least 2 siblings with schizophrenia, bipolar disorder, or Alzheimer's Disease). The data management and cell repository contracts will store and maintain clinical information as well as the lymphoblast cell lines needed for genetic analysis.

3. The 'Natural Products Screening Program' contract was let in FY 1989 to screen natural and synthetic compounds for their pharmacological interaction with nervous system receptor sites.

4. In FY 1990, the NIMH established a new branch to focus on molecular and cellular studies of brain function. In FY 1991, the budget proposes to fund a new center of excellence in the area of molecular neurobiology.

5. The NIMH is presently evaluating the research proposals received and is preparing a statement on new directions and priorities in the area of Mathematical and Theoretical Neuroscience.

6. In FY 1989, the "National Neural Circuitry Data Base" contract was awarded to the Institute of Medicine, National Academy of Sciences to carry out a study and report on the desirability and needs of the neuroscience community for this data base. This report on Brain Mapping is due in December 1990.

The Decade of Brain activities planned for the future include:

1. Based on the report from the Institute of Medicine, initiate activities to establish a computerized set of databases of all knowledge of the brain in an interactive textual and graphic format.

2. Establish a program to promote and facilitate the incorporation of advances in the chemical and physical sciences into the areas of brain research. For example, new non-invasive imaging techniques; and development of an implantable-synthetic micro neurocircuit.

3. Establish a Brain-Grant Colleges program. This would be modeled after other similar programs in land - sea - and space grant programs to establish a network of University-based brain sciences centers which would serve as focal points for a neural network database, enhance training of future brain scientists, foster technology development and transfer of knowledge between public and private sectors.

Question. To what extent has the NIMH coordinated its programs and efforts with the National Institute of Neurological Disorders and Stroke?

Answer. The NIMH Director and the National Institute of Neurological Distorders and Stroke (NINDS) Director meet on a regular basis to discuss issues. In addition, the Deputy Director of each Institute sits as an ex-officio member on the National Advisory Council of the other Institute.

An innovation begun last year by the Society for Neuroscience reflects the partnership in neuroscience research. The Institute Directors alternately continue to write a column in the monthly newsletter of the Society. This not only provides a vehicle for communicating to the field, but provides members of the Society with an open forum for responding to the statements.

NINDS and NIMH continue to jointly support the Brain Tissue Bank Program. Under this program, the two Institutes have a 16 year history of providing researchers with human post-mortem brain samples through the joint funding of two university-based brain tissue resource programs (McLean and UCLA).

The two institutes continue to interact on AIDS research and nervous system involvement in HIV infection. For example, two program announcements have been issued jointly by NINDS and NIMH, one on Central Nervous System Effects of Human Immunodeficiency Virus Infection: Neurobiological, Neurovirological, and Neurobehavioral

Studies and the second on Brain, Immune System, and Behavioral and Neurological Aspects of Human Immunodeficiency Virus Infection.

CHILD AND ADOLESCENT MENTAL HEALTH

Question. Would you briefly summarize the new National Plan for Research on child and Adolescent Mental Disorders prepared by the National Advisory Mental Health Council? What resources are necessary to fully implement this plan?

Answer. The National Plan for Research on Child and Adolescent Mental Disorders was developed because the mental disorders of childhood and adolescence are among the most devastating and least understood diseases of humankind. The research in this area has lagged behind comparable research on adult disorders. Under this plan, major new research initiatives are being developed to increase the understanding of the causes and determinants of child and adolescent psychopathology; determine the effectiveness of biologic, psychotherapeutic, and social treatments; develop more effective service delivery systems; and enlarge our cadre of qualified, committed researchers.

This plan entails increasing significantly the number of clinical and neuroscience research centers focusing on various aspects of child and adolescent mental disorders (e.g., developmental neurobiology, genetic studies of the severe mental disorders of childhood, suicide in children and adolescents, psychopharmacologic treatment study centers, etc.); a provision of financial and scientific support for the career development of 90 additional child and adolescent mental health researchers; the creation and funding of 25 institutional training projects across the nation to train future researchers; and substantial increases in the number of individual grants awarded to qualified investigators.

In FY 1991 the President's Budget includes $111.9 million for the National Plan for Research on Child and Adolescent Disorders.

NATIONAL INSTITUTE ON DRUG ABUSE

Question. I understand the National Institute on Drug Abuse Technical Review Meeting on Anabolic Steroid Abuse concluded that the long term health effects of these drugs are largely unknown. This void of information unfortunately has delayed the formulation of an effective prevention and intervention strategy. Is NIDA currently funding any research examining the long term effects of anabolic steroid use? If not, why? Is funding included in the FY 1991 budget to support research in this area?

Answer. NIDA held a technical review on anabolic steroid abuse on March 6 and 7, 1989 to assess the available information on anabolic steroid abuse and to define future research needs. The monograph resulting from this review is being edited for publication this summer. The technical review highlighted many areas in which information is lacking or insufficient and, as a result, NIDA is seeking to develop a program on anabolic steroids which will include research on the incidence, prevalence, causes, and consequences of steroid abuse and the development of prevention and treatment programs. A program announcement is being developed to solicit grants in this area. Researchers who have contacted NIDA with inquiries about support for studies on steroid abuse have been encouraged to submit applications. Currently seven proposals have been reviewed. One has been funded and at least one more will be funded this year. It is difficult to predict the number of applications that will be funded in FY 1991, but the issuance of the program announcement in this area should result in an increased number of applications. Funds are included in the FY 1991 budget for research in this area.

In FY 1987 and FY 1988 NIDA supported research on anabolic steroids through a contract which was part of our abuse liability program. These animal studies evaluated steroids for their effects on the central nervous system, and found that steroids do not have psychoactive properties. There is, however, some evidence that dependence on anabolic steroids may occur and this will be investigated in future studies.

In addition, beginning last year, questions on anabolic steroid use were included in the National High School Senior Survey. Current data indicate that three percent of high school seniors report using anabolic steroids at least once. The inclusion of these questions will allow us to evaluate trends in the use of these substances in high school seniors.

NIDA has also been assigned a lead role in the formation of an Interagency Task Force on Anabolic Steroid Abuse to coordinate Federal efforts to address this problem. The Task Force will be co-chaired by the Associate Commissioner for Health Affairs of the FDA and the Director of NIDA.

QUESTIONS SUBMITTED BY SENATOR TED STEVENS

NIMH INTRAMURAL PROGRAM

Question. Can you briefly describe some recent progress made in the field of mental illness in the intramural program of NIMH?

Answer.

Schizophrenia

Studies continue to suggest that brain atrophy is a hallmark of schizophrenia. Using rather sophisticated imaging techniques, including CT and MRI scanning, our research group at Saint Elizabeths has shown that brain atrophy is an early event in the course of schizophrenia that may even precede the onset of illness. Studies in discordant identical twins have shown that the ill twin has a larger ventricular brain ratio in virtually every twin pair. This indicates some degree of brain atrophy in the ill twin, despite an identical genetic background. These studies have also provided evidence that the brain atrophy may be in the temporal lobes. The findings are consistent with postmortem neuroanatomical studies suggesting degeneration of the parahippocampal gyrus and other areas of the temporal lobe.

Inhibition of Cocaine Craving by Carbamazepine

In intramural animal studies, it has been shown that chronic carbamazepine administration in diet blocks the development of cocaine- and lidocaine-kindled seizures. Since the seizures are particularly lethal, the animals often do not survive more than one to two episodes; carbamazepine blocks kindling activity and lethality. The only effective regimen is chronic, long-term administration. The resulting clinical caveat is that the cocaine addict must be disciplined enough to maintain chronic carbamazepine intake before it proves effective.

Cannabinoid Receptors

The first autoradiograms showing the distribution of cannabinoid (marijuana) receptors in brain have been produced by intramural investigators. The presence of these proteins on cell membranes suggests that there may be an as yet undiscovered natural messenger chemical in brain similar to THC. The newfound ability to radioactively tag these proteins will facilitate their purification, cloning and characterization. This work may lead to new medical uses for cannabinoid compounds.

Another group of intramural scientists has successfully isolated a full-length cDNA that encodes a cannabinoid receptor. Distribution of the mRNA which corresponds to this cDNA will be examined: to determine whether there are other cannabinoid receptors; and to study the pharmacological, physiological and biochemical properties of this receptor. The assay will be used to detect and ultimately isolate endogenous cannabinoids from the brain.

AIDS/Peptide Inhibitor of HIV Infection

In a collaborative venture, intramural investigators have continued to search for and characterize peptide analogs capable of inhibiting HIV infection. For example, they have reported that benzylated derivatives of CD4 (81-92) can block infection in vitro. They are searching for more potent compounds and preparing to test their candidates in SIV-infected monkeys.

AIDS/Quinolinic Acid

Quinolinic acid, a naturally occurring and potentially neurotoxic byproduct of the metabolic breakdown of tryptophan, is normally present only in trace amounts and fleetingly in the brain. However, intramural investigators have found markedly increased levels of quinolinic acid in CSF of patients with AIDS dementia. CSF levels of this toxic metabolite correlate with dementia ratings in these patients, suggesting that it may play a role in the pathogenesis of AIDS dementia.

Alzheimer's/Galanin

One group of IRP scientists is finding that neuropeptide modulators of brain cholinergic activity can affect experimentally-induced memory impairment in animals and humans and may hold promise in treating Alzheimer's disease. These studies focus on galanin, a peptide that coexists with acetylcholine in neurons that mediate memory processing. Using an animal model of Alzheimer's disease, they found that while acetylcholine improves the maze-running performance of rats whose memory systems are chemically impaired, this beneficial effect of acetylcholine can be inhibited by galanin. This work suggests that a drug that antagonizes galanin might help Alzheimer's patients, whose acetylcholine systems are similarly impaired.

Alzheimer's/Muscarinic Receptors

Using a prototype SPECT (Single Photon Emission Computed Tomography) scanner, intramural investigators have for the first time visualized the location of cholinergic neurotransmitter systems in the living human brain. The scans, which trace the uptake of iodinated QNB (a cholinergic antagonist), reveal the distribution of muscarinic acetylcholine receptors or binding sites on cell surfaces. Major deficiencies in these cholinergic receptors are evident in the brains of Alzheimer's patients studied.

Arthritis

In an inter-institute initiative with the Arthritis Institute, IRP scientists have studied the possible relationship between the HPA (hypothalamic/pituitary/ adrenal) axis and its regulation by higher cortical areas in the development of arthritis. It has been found that the HPA axis is far less responsive to various lymphokines and other immune/brain mediators in arthritis susceptible strains of rats. These studies are now being carried out to see if a similar defect exists in a clinical population of arthritis patients.

Question. Are you having difficulty attracting and retaining senior level scientists in the intramural program? How many senior level scientists working outside the Federal government has NIMH been able to attract to the intramural program over the past decade? How many senior intramural scientists has it lost?

Answer. Yes, the NIMH Intramural Research Program is having difficulty attracting and retaining senior scientists, particularly because of salary limits which often are 1/2 what a scientist could make at a university. Only one (1) senior level scientist working outside the federal government was recruited by the intramural program in the last decade. However, in less than two years this scientist left the intramural program for a position with private industry. Other senior scientists that the NIMH attempted to recruit, including a molecular biologist from Purdue University and a molecular geneticist from the Whitehead Institute, have stated that the salary levels are not competitive.

The NIMH intramural program has lost at least seven senior investigators in the last four years.

Question. What factors do you feel are responsible for this difficulty? Do you feel that salary levels are an important factor?

Answer. Although the SES pay rates that may go into effect in January 1991 may be beneficial in retaining the most senior scientific leaders, we will continue to have difficulty in attracting and retaining top level investigators at the GS13-15 levels.

Other factors that attract researchers to the private sector include portable retirement systems; tuition remission for children of employees; and, in private research organizations, various stock option packages.

Question. Do you feel that universities and government laboratories are being drained of their best researchers because of the attractions offered by industry?

Answer. This is such a recent phenomena that the full effect of industry recruitment has not been felt. However, the one senior scientist recruited by the NIMH intramural program in the last decade left the federal government for private industry and received twice the salary. In the oncoming years we expect that industry, with its more lucrative salaries and larger benefit packages, especially for scientists with Ph.D degrees, will be a major competitor for the most talented researchers.

NIMH FUNDING FOR ALASKAN NATIVES AND NATIVE INDIANS

Question. How much did NIMH spend in programs specifically targeted to Alaska Native and American Indian populations in FY 1989? What is budgeted for fiscal years 1990 and 1991? Is NIMH doing all it possibly can to address the needs of these populations?

Answer. In fiscal year 1989, NIMH invested a total of $5.8 million in projects addressing the mental health concerns of American Indians. Of this amount, at least $1.8 million was for research activities. In fiscal years 1990 and 1991, the NIMH has budgeted $7.7 and $6.9 million; respectively, and of those amounts $3.0 and $3.1 will be for research activities, respectively. NIMH projects include investigator-initiated research that will increase the participation of American Indian scientists in NIMH programs in the future, clinical training programs to ensure the availability of American Indian mental health service providers, and mental health services demonstration programs that will improve the quality and range of services provided to American Indians who are mentally ill.

Question. Briefly describe your mental health programs targeted toward these two groups, including what steps have been taken to assure that they are responsive to the unique cultural needs of these two groups.

Answer. The centerpiece of NIMH research support efforts directed toward Native Americans is the National Center for American Indian and Alaska Native Mental Health Research at the University of Colorado. The primary objectives of the Center, initially funded in 1986, are to identify the psychiatric and psychological problems affecting American Indian and Alaska Native populations, to promote and coordinate research projects designed to improve mental health service delivery systems, and to provide clearinghouse services to individuals interested in Native American mental health research. This Center is providing leadership in developing culturally appropriate instruments for assessing depression in several tribal groups and in studying factors associated with suicide among American Indian youth.

American Indians are underrepresented among scientists in the mental health research field as well as among clinicians providing mental health services. The Institute is funding several meritorious programs to address this problem. For example, the University of New Mexico Minority Access to Research Careers (MARC) Program provides training in basic research methods and analytic techniques for American Indian and other minority honors undergraduates to prepare for graduate studies leading to a doctoral level degree in one of the scientific fields underpinning alcohol, drug abuse, and mental health research.

Four institutional clinical training grants (University of California-Berkeley, University of Colorado, Arizona State University, and Utah State University) were awarded to programs in nursing, social work, and psychology. These grants will support American Indian trainees and will improve the cultural content of the existing curriculum to ensure cultural relevance for American Indian trainees and to sensitize non-Indian trainees to the bicultural and bilingual needs of American Indians.

Question. Given the extremely high rates of suicide, depression, and alcohol and drug abuse among these populations, how have your programs matched those rates of dysfunction?

Answer. The NIMH has provided leadership in developing a program announcement--Epidemiologic and Services Research on Mental Disorders that Co-occur with Drug and/or Alcohol Disorders among American Indians and Alaskan Natives. This new initiative, a collaborative undertaking with NIDA and NIAAA, is intended to encourage research on the prevalence of mental disorders that co-occur with drug and/or alcohol disorders. We expect to extend the knowledge of the prevalence and treatment of mental disorders ascertained from the Epidemiologic Catchment Area (ECA) and other major epidemiologic and services use studies.

NIMH PROGRAM EVALUATIONS

Question. How do you ensure that these programs have an adequate evaluation component sufficient to offer results and guidance to the communities and populations they study?

Answer. The programs funded by NIMH are research projects which aim to make reliable inferences from data or results. The peer review process used to assist NIMH in selecting scientifically meritorious projects ensures that the research design is appropriate to the question being researched and will lead to results that could be used to benefit communities and populations.

QUESTIONS SUBMITTED BY SENATOR WARREN RUDMAN

MENTAL HEALTH RESEARCH

Question. Last year, the conferees on the FY 1990 appropriation bill provided a $30 million increase above the budget request for non-Aids mental health research supported by the National Institute of Mental Health. The recommendation recognized the strides which have been made in diagnosing serious mental illness as a result of the new noninvasive imaging techniques for visualizing the structure and function of the brain and the potential this new technology holds for treating serious mental illness. I am concerned that the FY 1991 budget proposal for Mental Health Research will not continue the progress made last year. New and competing research grants at NIMH are proposed to decline by 31 percent and the Schizophrenia program--generally identified as the Institute's highest priority--does not keep pace with inflation.

Will the budget request for research slow the continued implementation of the National Plan for Research on Schizophrenia and the Brain?

Answer. "The National Plan for Research on Schizophrenia and the Brain" represents a comprehensive approach to implementing the visionary goals of the "National Plan for Research on Schizophrenia" and the "Approaching the 21st Century: Opportunities for NIMH Neuroscience Research" plans. The recommendations in these reports were not, however, developed by the Administration and do not take into consideration support needed for other competing research priorities. NIMH is currently reviewing these plans in light of the final budget estimates for FY 1990 and has considered their recommendations in developing the President's proposal for FY 1991.

Since substantial elements of the two plans are complementary, managing and tracking the investments in their implementation must account for those research activities which support both initiatives. This conceptual scheme, "The National Plan for Research on Schizophrenia and the Brain", provides a yardstick to measure progress on the plans, both individually and jointly.

Question. In the field of mental health, what is your payline--what is your general priority score cutoff for new competing research project grants, and how does that compare with fiscal year 1990?

Answer. For NIMH research project grants, the priority score payline is projected at 120 in FY 1991, compared to the projected FY 1990 payline priority score of 130.

The decrease in priority score can be attributed to the significant increase in continuation costs at NIMH, which has limited the funds available for new applications and competing renewals.

Question. Are your mental health grants funded at levels recommended by the review groups, or are you operating under some sort of funding plan? Do you expect downward negotiations under this year's budget?

Answer. The NIMH has established a Non-AIDS funding policy requiring a negotiated reduction in FY 1990 averaging 10 percent from levels recommended by the review groups.

Question. Are individual research project grants experiencing unreasonable increases? How much of this is due to expanding salaries for principal investigators? Would you support placing a cap on the salaries of principal investigators with Federally-supported grants?

Answer. Individual research project grants are not experiencing unreasonable increases. For example, in FY 1990 the average cost of ADAMHA's new and competing research project grants rose only 6.1 percent over FY 1989. The increases in grants costs are attributable to many factors including the high cost of new technologies, the greater complexity of biomedical research requiring a variety of expertise and thus more contract support, and inflation. The President's budget again proposes capping the salaries paid through extramural awards from ADAMHA and NIH at $120,000, as they were in FY 1990.

DRUG ABUSE RESEARCH

Question. The Office of National Drug Control Policy is establishing a Research and Development Committee to work with the Alcohol, Drug Abuse and Mental Health Administration to develop and refine nation drug-related research goals.

Do you anticipate that this new committee will recommend changes in the direction of your agency's ongoing drug-related research?

Answer. ADAMHA views the establishment of the Research and Development Committee as an opportunity to enhance existing efforts and to incorporate more long term approaches into the national drug strategy. National Drug Control Strategy III will derive recommendations from the work of this and other committees chaired by ONDCP.

Question. The general measure of the adequacy of our Federal research activities is the number of new and competing research grants which can be awarded in any given fiscal year. For fiscal year 1991, new and competing research grants at the National Institute on Drug Abuse would decline by 11.8 percent from 278 grants to 245 grants. Are you satisfied what drug abuse research efforts are adequate, given the general lack of knowledge about "what works" in the area of drug treatment?

Answer. While the number of new and competing continuation grants funded each year is an important measure of the adequacy of funding, it is not the only one. In FY 1991, NIDA will support a total of 796 project grants, 70 more than the FY 1990 level and 206 more than were supported in FY 1989. That amounts to a 34 percent increase in the number of grants over a two year period. I have no hesitation in saying that this funding level is adequate. I should also point out that the budget will allow NIDA to increase its research on drug abuse treatment by $12.6 million, or 21 percent over the FY 1990 level.

In addition to NIDA research grants, ADAMHA funds substance abuse research through the Treatment Outcome Research line and through the Block Grant Set-aside. Treatment outcome research will increase by $532,000 to $8.3 million ($4.2 million for drug abuse) from FY 1990 to FY 1991 and will increase $6.1 million over FY 1989. Research funded through the block grant set-aside will increase by $14.5 million to a total of $74.1 million ($24.5 million for drug abuse activities) in FY 1991. This is $33.9 million over FY 1989. Set-aside research will fund efforts in data collection, services research and technical assistance programs.

QUESTIONS SUBMITTED BY SENATOR PETE V. DOMENICI

MENTAL HEALTH RESEARCH

Question. With the strong support of the distinguished Chairman and Ranking Member of the Subcommittee, the Congress took a significant step forward in launching a National Plan for Research on Schizophrenia in the 1990 appropriations bill.

I cannot emphasize too strongly the absolute necessity of aggressively implementing the schizophrenia research initiative. The time for a "silent war" against serious mental illness is over. Mental illness is a serious health problem afflicting some 31 to 41 million Americans annually in clearly diagnosed As much as 30 to 50 percent of the homeless population suffer from mental illness, as do 12 million children.

To put these statistics into another perspective, few realize that schizophrenia is twice as common as Alzheimer's disease, five times more common than multiple sclerosis, six times more common than insulin-dependent diabetes, fifty times more common than cystic fibrosis, and sixty times more common than muscular dystrophy.

It is obvious from these statistics that mental illness is a significant source of suffering but also a significant cost to society. For schizophrenia alone, its estimated cost to society in treatment costs and lost income is $40 billion annually.

Since NIMH designated schizophrenia as its foremost research priority in 1986, how much has it spent on research into schizophrenia? Could you provide these funding levels by fiscal year?

Answer. The following table displays the NIMH total research effort on schizophrenia from FY 1987 through the FY 1991 Request.

	Dollars in Thousands				
	FY 1987 Actual	FY 1988 Actual	FY 1989 Actual	FY 1990 Estimate	FY 1991 Request
Research...	$32,066	$54,986	$82,618	$95,745	$99,315

Question. Would you provide for the Subcommittee the major goals NIMH hopes to accomplish with the requested $481.9 million NIMH research and research training budget in FY 1991?

Answer. Recent discoveries in the basic and clinical sciences applicable to mental health and disorders as well as a thorough review of the opportunities and unmet needs in several fields have focused NIMH research goals for FY 1991 and the first half of the Decade of the Brain on four major research plans and several additional priority areas. These plans and areas share four common themes: the need to capitalize on the recent great scientific opportunities that now provide unprecedented hope that many still-puzzling mental disorders will be conquered in the foreseeable future; mechanisms to achieve the scientific advances underlying the "Decade of the Brain"; recognition of the necessity to develop the talents and skills of a new generation of scientists dedicated to mental health research; and strong encouragement and support for academic researchers to form collaborative working relationships with public mental health service settings, the Public-Academic Liaison (PAL) Program.

Two related plans are underway with these implementation strategies combined into the "National Plan for Research on Schizophrenia and the Brain". The National Advisory Mental Health Council has developed the third plan, "The National Plan for Research on Child and Adolescent Mental Disorders" in response to needs and opportunities recognized in the FY 1990 Congressional Appropriations Report. The fourth plan, "A Research Strategy to Improve the Care of the Severely Mentally Ill", is nearing completion and should be available by the time final allocations of FY 1991 research funding are made.

In addition, NIMH is pursuing important Institute-wide programs of research. Alzheimer's disease is among the most devastating of health problems, both for the patient and the entire family. NIMH research will follow-up solid recent advances in this field. Suicide, a major cause of mortality, has been an area of Congressional and Institute concern. NIMH has embarked on a long-term program to enhance understanding and prevention of suicide. Homelessness and its relationship to mental illness are also major priorities of the Administration and the Institute. In FY 1991, the Institute will also follow-up the new rural mental health research programs initiated by the FY 1990 Congressional action. A final area of research priority is HIV/AIDS research. The Institute is pursuing basic research in AIDS related neuroscience and behavior, as well as clinical, services and prevention research.

Question. Although the FY 1991 request for NIMH research and research training (excluding AIDS) represents a $28 million, or 6 percent, increase, the proposed funding level falls far short of implementing the recommended National Plan for Schizophrenia Research and the Decade of the Brain initiatives. What levels of funding would be needed to fully implementation of these research initiatives in FY 1991?

Answer. The recommendations in the National Plan for Schizophrenia Research and The Decade of the Brain do not necessarily reflect the priorities of the Administration. These reports were prepared by outside sources and do not take into account other ADAMHA funded scientific priorities.

To fully implement the National Plan for Schizophrenia, an additional $92 million is needed. The Decade of the Brain falls short by $138 million. Since there is a measure of overlap between these plans, a total of $170 million would be needed to fully implement the combined plans. However, funding for this project was considered among many competing demands on resources such as the "War on Drugs" and Head Start.

NATIONAL PLAN FOR RESEARCH ON SCHIZOPHRENIA AND THE BRAIN

Question. The President's FY 1991 budget proposes $481.9 million for research and research training through the National Institute of Mental Health (NIMH), excluding AIDS. This funding level is $28 million, or 6 percent, above the FY 1990 funding level.

The budget proposes a consolidation of two major mental health research initiatives -- The National Plan for Research on Schizophrenia and the Decade of the Brain -- into a single plan.

Would you please provide your rationale for this consolidation and the revised research plan the Administration intends to follow if this combined plan is implemented?

Answer. The recent presidential proclamation declaring the "Decade of the Brain," which formalized a congressional resolution approved by the One Hundred and First Congress, recognizes the extraordinary opportunities for mental health research. The President's FY 1991 Budget provides increased funding to support the goals of the "National Plan for Research on Schizophrenia" and the "Approaching the 21st Century: Opportunities for NIMH Neuroscience Research" plans. In presenting the FY 1991 budget proposal, these obviously related plans have been conceptually combined to recognize their complementary elements and shared objectives.

The original research agendas of both plans remain viable and visionary. The Institute's continuing national leadership in developing a firm scientific foundation for the diagnosis, treatment, and prevention of mental disorders has contributed significantly to the mental health field's unprecedented ability to reduce the enormous social and personal costs of mental illness. Equally important for the 15 to 20 million Americans likely to become mentally ill during their lifetime, the explosion of scientific knowledge over the past decade has created new hope that many now-puzzling mental disorders will be conquered in the foreseeable future.

Question. Would you provide funding details for FY 1990 and the FY 1991 budget request for the components of these research initiatives?

Answer. The following table displays the amounts estimated in the FY 1990 and FY 1991 budget request for these research initiatives.

	FY 1990 Estimate	FY 1991 President's Budget
Schizophrenia Plan	$ 95,745,000	$ 99,315,000
Decade of the Brain	$180,161,000	$191,627,000
Combined Plans	$221,306,000	$233,706,000

Question. What is NIMH's estimate of the research funding that will be devoted specifically to schizophrenia?

Answer. The NIMH FY 1991 estimate for the total research effort on schizophrenia is $99,315,000.

Question. How much funding is requested to begin implementation of the National Program of Research to Improve the Care of the Severely Mentally Ill, the report for which should be completed early this year?

Answer. No good estimate is available at this time. Further analysis of the funding situation will be undertaken once the report has been reviewed by consultants and the National Advisory Mental Health Council, which has established a sub-committee to consider the recommendations and develop its own position on this plan.

NIMH RESEARCH GRANTS

Question. The ADAMHA budget justifications indicate that approval of the President's proposed $481.9 million research and research training budget for the National Institute of Mental Health (NIMH) would result in an award of approximately 16 percent of the grants approved through the scientific review process. The award rates for FY 1989 and FY 1990 were 31 percent and 26 percent, respectively. While the budget indicates that the requested funding level will retain the level of investigator-initiated research projects grants at about the 1990 level of 1,145, competing awards will decline from 404 in FY 1990 to 278 in FY 1991.

Would you provide the Subcommittee with an explanation of the factors affecting the change in the estimated number of grant awards?

Answer. The biggest single factor in the reduction of NIMH new/competing grants from 404 in FY 1990 to 278 in FY 1991 is a significant increase in continuation costs, which has limited the funds available for new applications and competing renewals. The total number of continuations rose from 526 in FY 1987 to 655 in FY 1989 and commitments to those continuations accounts for a substantial proportion of NIMH's total research budget. In FY 1989, for example, continuations represented 62 percent of the total number and total dollars devoted to research project grants. In FY 1991, they will represent 76 percent.

This growth in NIMH commitments is also affected by the length of grant awards. In response to requests from the field, NIMH has recently added a number of grant mechanisms that provide noncompeting research funding for longer than the traditional 3-year period. The MERIT (Method to Extend Research in Time) award, begun in FY 1987, provides for up to 10 years of support before competitive renewal is required. The very important and useful FIRST (First Independent Research Support and Transition) award, also begun in FY 1987, provides support for 5 years. MERIT awards have increased from 1.6 percent of the total research program grants in FY 1987 to 8 percent in FY 1989, and FIRST awards have increased from 1.7 percent to 9.7 percent. The net effect of these increasing commitments, combined with inflationary growth in the average cost of individual research projects, has been to limit the amount of money available for funding new/competing grants.

Question. Could you provide for the record a comparison of the number of grants and the estimated award rates associated with the President's (non-AIDs) budget request for research and related activities for the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and the various National Institutes of Health?

Answer. The comparison provided represents the overall President's request.

	1990 Estimate		1991 Estimate	
	RPGs	Award Rates	RPGs	Award Rates
ADAMHA.....	2,342	33.0%	2,403	20.0%
NIH........	20,316	24.1%	20,439	25.4%
NIDA......	726	38.2%	796	28.5%
NIAAA.....	467	48.2%	462	19.9%
NIMH......	1,149	26.5%	1,145	16.0%

Question. As you know, a coalition of mental health groups proposes a 'professional judgment' budget for NIMH every year. This is particularly noteworthy because many of these same groups actively participated in drafting the National Plan for Schizophrenia Research. The National Alliance for the Mentally Ill (NAMI) has proposed a $650 million non-AIDS research budget for NIMH in FY 1991. What further initiatives could NIMH accommodate with an enhanced budget request as proposed by NAMI?

Answer. The National Alliance for the Mentally Ill (NAMI) developed this budget without viewing it in terms of competing high priorities such as the "War on Drugs", AIDs, and Head Start. If the $650 million budget proposed by mental health groups was available, the National Institute of Mental Health (NIMH) would proceed with implementation of the FY 1991 elements of The National Plan for Research on Schizophrenia, the Report on the Decade of the Brain, and the new National Plan for Research on Child and Adolescent Mental Disorders.

The Child and Adolescent Plan developed by the National Advisory Mental Health Council, requested by the Congressional Appropriations Committees, would mount a systematic assault on the mental disorders that afflict the Nation's youth by increasing the understanding of the basic causes of child and adolescent mental disorders; determining the effectiveness of biological, psychosocial, and other treatments; providing a research base for more effective service delivery; and enlarging the number of researchers committed to this field.

In terms of increased research projects, this alternate budget would support: the award of 625 new and competing research projects grants, 221 more than in FY 1990; expansion of the Clinical Research Centers programs with 14 new centers so that research and research training integral to the research plans may be undertaken; and an increase to the Research Training Program by 934 training positions to prepare more scientists for careers in mental health research.

In addition to the resource needs for implementation of the Institute's major research plans, the NIMH would also award grants to: undertake additional linkage studies to identify genes that underlie such severe metal disorders as schizophrenia, manic-depressive disorder, and Alzheimer's disease; pursue further investigations into the biological function of amyloid in Alzheimer's disease that may lead to diagnostic and possibly therapeutic approaches to the problem of Alzheimer's; further evaluate the impact of a very promising new antipsychotic drug, clozapine, on subgroups of schizophrenic patients who have not responded well to standard medications; expand brain imaging studies to clarify the role that brain structure, function and neurochemicals play in attention deficit/hyperactivity disorders, obsessive compulsive disorder, and dyslexia; increase the national base of functional brain imaging facilities which are specifically dedicated to research on mental disorders; and extend magnetic resonance imaging studies on identical twins, one of whom is afflicted with schizophrenia, to determine subtle signs of reduced brain volume in the patient.

This budget level would also permit an almost tripling of the funded research demonstration grants on homelessness and its relationship to mental illness. These studies would focus on epidemiological research, services research, and service systems research on both homeless mentally ill adults and homeless families with children who are at risk of several emotional disturbance.

COSTS OF MENTAL HEALTH DISEASE

Question. I mentioned earlier the estimates of the economic costs (treatment and lost income) to society of schizophrenia alone--$40 billion annually. Such analysis cannot be precise, but even rough estimates are useful. An analysis of not only how much mental illness costs our country, but how much it is adding to our federal deficit would point out how federal policy can be penny-wise and pound-foolish. Health overall and mental health, in particular, serve as examples. Our society, and the Federal government, pour billions into caring for people once they are stricken with a terrible diseases or illness, but we spend relatively little minimizing their chances of becoming mentally ill or with some other illness or disease.

Have you any even rough analysis of the costs borne by federal programs (Medicare, Medicaid, lost tax revenue, other programs) of mental illness?

Answer. In 1988 an estimated 714,230 persons received Social Security Disability Insurance (SSDI) benefits amounting to an estimated $4.5 billion for disability on the basis of mental impairment. In the same year, an estimated 539,230 persons received

Supplemental Security Income (SSI) benefits totalling an estimated $1.6 billion for disability on the basis of mental impairment. Estimated costs incurred by other Federal programs for mental illness include $1.8 billion by Medicare in 1987, $1.4 billion by Medicaid in 1988, $1 billion by the Department of Veterans Affairs in 1989, and $237 million from the Alcohol, Drug Abuse, and Mental Health block grant in 1990. These figures, which do not include all Federal programs that assist mentally ill persons and emotionally disturbed children, indicate that the Federal government spends in excess of $10 billion annually on mental illness. No comparable estimates are available on Federal tax revenues lost as a result of mental illness.

Question. Would you compare that to federal spending for research into curing mental illness, and other programs to help prevent mental illness?

Answer. Virtually all Federal funds for research on and prevention of mental illness are channeled through the National Institute of Mental Health and the Department of Veterans Affairs. In 1989 the NIMH had a total budget of $450 million and the VA expended $11 million on research on mental illness, for a total of $461 million. More than $10 billion is expended annually by the Federal Government to treat and assist persons who are mentally ill.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

NATIONAL HEALTH SERVICE CORPS (NHSC)/IOWA

Question. The National Health Service Corps is so important to my State: there are 23 health manpower shortage areas in Iowa, where the physician to population is 1:3500. In 1988, 26 Corps doctors were practicing in those areas. Now there are just 12 doctors left, and seven of then will complete their service obligation in 1990. According to your staff, no new placements are planned for Iowa in 1990 or 1991.

It's the same story across the country: we would need over 4,200 doctors to remove the designation of "health manpower shortage area," yet the Department is only recruiting for 811 positions. And while 630 doctors will complete their service obligation this year, just 341 new doctors are in the National Health Service Corps pipeline through 1995.

How many health professionals will be place in health manpower shortage areas through the Corps loan repayment and scholarship programs this year?

Answer. There are about 120 scholarship obligors available for assignment and we estimate that there will be between 80 and 100 loan repayment obligors during 1990. Using the 1987 level of obligors as a baseline number, there are over 1,200 vacancies. It is anticipated that the number will increase by over 400 during 1990 as result of obligors completing their obligation and the lesser number entering service.

Question. How many NHSC positions could be filled this year if funding were available?

Answer. At this point in the fiscal year, additional funding would have a negligible effect on 1990 placements.

Question. The budget proposes to vastly increase funding for the scholarship and loan repayment programs by $55 million in FY 91, but would target the funds to disadvantaged and minority students.

What impact would this proposed budget have on my State and other rural states?

Answer. If the budget request of $64 million is enacted, the following distribution is projected:

Approximately $36 million will be used to fund approximately 464 multi-year scholarships at an anticipated average cost of $78,125;

Approximately $28 million will be used to support approximately 921 single year Federal loan repayment agreements at an anticipated average cost of $30,000.

Final decisions regarding the distribution of these funds will be made during FY 1991 when a more accurate assessment of the needs and opportunities for the program is possible.

In conjunction with the proposed minority health initiative, additional sites, both urban and rural, would be included on the vacancy listings specifically for minorities. These sites will provide settings with which they would be more comfortable and where they would be more likely to stay.

The impact on health care in rural States would be addressed primarily through the awarding of scholarships, and to a lesser extent through loan repayments as described above. The Scholarship program can direct obligated practitioners to those areas of rural America for which it has historically been difficult to recruit. Through use of the approved vacancy list for the Federal Loan Repayment Program, some loan repayment practitioners will also match to those areas.

In awarding scholarships, the program will continue the interview process used to ensure students understand that the majority of assignments for fulfillment of the service obligation will most likely be in rural areas. In addition, in support of the Secretary's initiative to increase minority practitioners in PHS programs, ethnicity will be considered as well as the commitment of the program in which they are enrolled to primary care. Information of student background: i.e., if raised in a health manpower shortage area; rural community; historically poverty sections of inner cities; COSTEP experience; prior work in CHCs or rural communities, are also evaluated and used in selection of scholarship awardees.

Question. There is discussion of legislation proposal to target NHSC funds and doctors toward specific diseases and maladies, such as AIDS and substance abuse.

If funding for the Corps becomes focused on specialty areas such as those, what would be the effect on the general program, specifically on underserved rural areas?

Answer. The National Health Service Corps is opposed to targeting physicians to special populations such as AIDS, substance abuse, etc., as it believes that placements in organized systems of care which include care for AIDS and substance abuse patients is a better utilization of scarce health manpower.

FUNDS FOR RURAL AND URBAN CENTERS

Question. Last year you reported that while 61 percent of community health centers are located in rural areas, and rural centers serve 50 percent of all health center patients, rural health centers were getting only 40 percent of federal grant funds. The Subcommittee's report called for eliminating this program and dividing funds between rural and urban centers in the same ratio as the patients are divided.

What progress have you made so far, and when will grant funds be divided equitably between rural and urban centers?

Answer. As a first step, we compared cost and revenue data for rural and urban health centers for a three year period to understand the factors that have contributed to the allocation inequity. While program expenditures reported for each of the three years remained fairly constant, with rural centers reporting 41 percent and urban centers 59 percent, the basic grant resource allocation showed a steady shift toward equity. Between 1986 and 1988, rural centers went from receiving 44 percent of the Section 329/330 grant resources to receiving 46 percent of these resources. This trend continued in fiscal year 1989 when the proportion of funds going to rural centers increased to 46.5 percent. With the centralization of the grants process, grantees are being evaluated more consistently against national criteria which is enabling BHCDA to address service delivery deficiencies for individual rural grantees. With the targeting of available resources to grantees with high need, we will ensure a more equitable distribution of resources.

Question. It's been years since there were any new community health center starts -- yet there are no centers in rural areas of Iowa, Montana, North Dakota, Nebraska, or so many areas of the nation's heartland that are in dire economic circumstances do not have health care services available.

Last year, we added $20 million to the CHC program, yet no new starts were considered for this program. which is supposed to make health care services more accessible to the residents of geographically isolated areas.

-- Has the department changed its policy on this?

Answer. There was a net addition of $25 million to the Fiscal Year 1990 budget for community and migrant health centers. Of this amount $11 million was earmarked for annualization of perinatal activities begun during 1989 ar existing centers.

The remaining $14 million was used to meet the increased costs of doing business at health centers including cost of living increases, malpractice insurance, and other cost increases. It was necessary to meet these increased costs of doing business in order to maintain our health care delivery capacity at current levels. Also provided from the increase was funding for retention and recruitment for Center physicians.

HELPING CENTERS RECRUIT STAFF

Question. When the Department evaluates community health centers to determine the amount of their federal grant, centers are penalized for having staff vacancies. This can result in small grant awards. I am concerned that rural and frontier health centers, which have a harder time recruiting staff, may be placed at an unfair disadvantage due to a performance grading system that penalizes them for staff vacancies.

--How does the Department assist centers to recruit staff?

--Do all centers receive this support?

--What funds are available to health centers that are having trouble recruiting for staff positions?

Answer. The Department is concerned with maintaining health care capacity in these communities to which it is currently providing services. If health centers are not able to maintain current capacity by attracting and retaining full-time physicians and mid-level staff, Federal support will be removed for that portion of delivery capacity which no longer exists, i.e. the unfilled vacancy.

The PHS Recruitment Program assists community and migrant health centers to recruit staff through a variety of mechanisms. We have a national marketing campaign which includes advertising in professional journals, direct mailings to health care professionals, exhibiting at national professional meetings, conducting residency program and school visits, and attending career days.

In addition we support State Primary Care Associations and State Cooperative Agreements Agencies to aid centers in locating and recruiting health professionals. We also contract with the American Academy of Family Practice (AAFP) and the National Medical Association to advocate for the personnel needs of community and migrant health centers.

Through these combined efforts, the PHS recruited approximately 100 physicians for service in community and migrant health centers. In addition, through the Federal loan repayment program 106 of the 112 practitioners matched are serving at either community or migrant health centers.

In FY 1989, the Bureau of Health Care Delivery and Assistance (BHCDA) recently awarded $23 million to community and migrant health centers to enhance the salaries and fringe benefits for their health care providers. All centers had the opportunity to competitively apply for these funds. Once awarded, these dollars become part of the centers' ongoing Federal support. Centers that offer competitive salaries and fringes will be effective competitors for health care professionals.

Technical assistance is provided and may occur at the national/regional/state or local level by Federal as well as contract staff. In preparation for the competitive grants referenced above, regional workshops were conducted to sensitize Federal and center staff on the importance of retaining and recruiting well qualified staff.

Additionally, centers can request cost of living adjustments to their salaries and fringes in the yearly submission of their grant applications.

Question. What have exit interviews of staff indicated about their reasons for leaving?

Answer. Since January 1 of 1990, there have been two sets of telephone interviews made to assist in the retention of health care providers. The first 55 NHSC obligors who had indicated they were leaving their assignments were queried concerning their reasons for leaving.

Most providers cited multiple reasons for leaving their current practice. Of the 55 providers, 20 cited lack of administration decision making, lack of control over their practices, and non-competitive salaries. Fifteen are considering staying but have not been able to complete negotiations for an acceptable salary/compensation level. The remaining individuals who are leaving are pursuing training opportunities, are moving to a different geographic location, or are joining other Federal programs.

The second group was comprised of 109 obligors who were completing their obligation and were undecided about their future plans. Of this group, 32 are going to leave, 24 are remaining at their current assignments, 8 have accepted assignments at other PHS facilities and 45 are still undecided.

While the PHS has and will continue to assist health centers in their recruitment efforts, the responsibility for recruiting and retaining medical practitioners who are not obligated to serve must by assumed by the centers.

MATERNAL AND CHILD HEALTH (MCH)

Question. The U.S. infant mortality rate is simply tragic. With all our vast resources and high technology, the Centers for Disease Control says we will not meet the 1990 goal of reducing infant mortality to 9 deaths per 1000 births overall, and 12 deaths per 1000 births for Blacks.

I was happy to see $27 million proposed for "one stop shopping" of maternal and child health services and "mom vans," but it appears that these services would be funded at the expense of the basic program: the budget proposes to fund the Maternal and Child Health block grant at the FY 90 post-sequester level.

In your opinion, how far is the proposed MCH budget going to move us toward the year 2000 goals (now cut in draft) of reducing infant mortality to 7 deaths per 1000 births overall, and 11 deaths per 1000 births among Black?

Answer. The increases proposed for "one-stop shopping" and "mom vans" contained in the Administration's fiscal year 1991 budget represent new money directed toward improving services for pregnant women and children. These funds are outside of the Maternal and Child Health block grant. While we are unable to predict the exact effect these programs will have on infant mortality rates, we are optimistic that the improvements sought will have a positive effect on access and subsequent health outcomes.

States will receive no additional funds under the 1991 budget request for Maternal and Child Health. However, States do have the flexibility to redirect their resources to their highest priorities. States will be required in their 1991 application for Maternal and Child Health funds to set forth their goals and objectives consistent with the Year 2000 Objectives.

Question. Last year, the Subcommittee added funds to the Maternal and Child Health block grant for maternal and child health handbooks, which would provide a home-based health record and basic information on babies' health and development to women and new families.

When will the handbooks be ready?

Answer. The Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) authorizes up to $1.0 million in each of fiscal years 1991, 1992 and 1993 for the development, field-testing and dissemination of a maternal and child health handbook. The law requires the production of the handbook by July 1, 1990, with completion of field testing by June 1, 1991.

The Office of Maternal and Child Health (OMCH) has established a work group to meet the legislative requirement. Planning discussions with the National Commission to Prevent Infant Mortality have occurred recently. A larger planning and development meeting including the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, the Childrens' Defense Fund, the Association for the Care of Children's Health, the Healthy Mothers/Healthy Babies Coalition and the National Commission for the Prevention of Infant Mortality, is scheduled to take place in March. Although there has been no specific appropriation for this activity in FY 1990, a limited amount of SPRANS funds is available to support the handbook development and to begin field testing and evaluation.

The OMCH expects that a handbook will be ready for field testing and evaluation on or about July 1. Field testing of the document for appropriateness of format and client acceptability should be mainly completed by the June 1, 1991 due date. Evaluation of the impact of the handbook on perinatal care, client knowledge, healthy behaviors, outcome of pregnancy and infant health status will be much more difficult to ascertain during this time period. Answers on the best use of this instrument -- for which populations and under what circumstances -- will also require additional time.

HEALTH PROFESSIONS/NURSING EDUCATION

Question. There is good news and bad news on health professions and nursing education this year. The good news is that there is a request for funding. The bad news is that it covers only a very few programs. Last year we provided $214.7 million for the Health Professions programs. This year's request is for $75.9 million and would eliminate 27 programs.

The $75.9 million would fund efforts to boost minority representation in the health professions. I think we can support that part of the proposal.

If some funds are restored to the health professions and nursing education programs, which programs do you think should be funded first -- which are doing the best job of filling gaps in the supply or distribution of health care providers?

Answer: If funds are added for health professions BHPr's multidisciplinary programs would be of the highest priority. These programs are the Area Health Education Centers (Sec. 781) and the Geriatric Educations Centers (Sec 301 & 789(a)). The second priority would be to fund primary care programs.

For nursing, the nursing special projects (Sec. 820) and the nursing practitioners/midwife (Sec. 822) would be BHPr's highest priorities.

Question: Which are doing the best job of filling gaps in the supply or distribution of health care providers?

Answer: The Area Health Education Centers, the Geriatric Education Centers, the primary care programs and the nursing practitioner/midwife programs are doing the best job in filling gaps in the supply and distribution of health care providers.

ALLIED HEALTH PROFESSIONS

Question. What is the Department's experience so far with the newly funded programs for allied health professionals and interdisciplinary training for practice in rural areas?

Answer. Under Section 796(a) of the Public Health Service Act--Allied Health Special Project Grants--there was $750,000 appropriated for FY 1990. It is estimated that there will be 7 to 10 grants awarded. There have been approximately 2,000 application kits requested and mailed. Applications are due (postmarked) no later than Feb. 12, 1990. Awards will be made in Fiscal Year 1990.

Under Section 799(a) of the Public Health Service Act--Grants for Interdisciplinary Training for Health Care for Rural Areas--there was $2.21 million appropriated for FY 1990. It is estimated that there will be 7 grants awarded averaging $300,000 per grant. Some 350 interested parties have requested application kits thus far. Mail-out date of kits, due date for applications and date for peer review are to be scheduled. Awards will be made by September 30, 1990.

MIGRANT HEALTH CLINICS

Question. How much of the migrant population is served currently by the migrant health centers program?

What factors limit this program from serving more migrant workers?

Answer. The migrant health program serves approximately 520,000 migrant and seasonal farm workers of which approximately 80 percent are migrant farmworkers. The program estimates that there are a total of 4 million migrant and seasonal farmworkers around the country. Therefore, the program serves about 10 percent of the migrant population.

The factors which limit the program from serving additional migrant workers are:

Lack of an adequate supply of providers (physician, mid-levels, and dentists) willing to work with this population.

Lack of adequate third party insurance coverage and ability of migrants to pay for services.

Because of the mobility of migrants, it is often difficult to reach them and bring them in for care. Centers have developed aggressive and comprehensive outreach programs which include transportation, mobile vans and educational screening programs which are designed to reach out to this population.

Unwillingness of farmworkers to take time off from work to seek medical care because to do so causes loss of income.

Question. The Committee requested that $500,000 of FY 90 funds be used to fund up to four demonstration State plans to address comprehensively the needs of migrant workers.

What is the status of this initiative?

Answer. We are in the process of developing eligibility, selection and review criteria for the State-wide environmental demonstration grants. The target date for submission of application is June 30, 1990, with awards to be issued by September 30, 1990.

ORGAN TRANSPLANTS

Question. I have here a letter from one member of the Board of Directors of the United Network of Organ Sharing (UNOS) to the other Board members. The letter alleges that the registration fee for placing patients on the organ waiting list was increased recently in an effort to generate additional revenue for UNOS, and is not justified by increased costs of listing patients in the registry.

Why are consumers being charged a fee to be listed in the UNOS system when federal funds are supposed to guarantee that individuals waiting for transplantation do not have this added expense?

Answer. The United Network for Organ Sharing (UNOS) which operates the Organ Procurement Transplantation Network (OPTN) under contract with HRSA has always charged a one-time fee for registering a transplant candidate on the computerized waiting list. Federal funding has never been intended to guarantee that transplant candidates would not be charged a fee for registration on the waiting list.

Question. Would it be possible for the Organ Transplantation Office in HRSA to maintain the registry?

Answer. Section 372 of the Public Health Service Act, requires that the OPTN, which maintains the waiting list of transplant candidates, be operated by a private, nonprofit entity under contract with DHHS, and Section 373 requires that the scientific registry of transplant recipients be maintained under a grant or contract with DHHS.

Question. What is the relationship between the Office and UNOS?

Answer. The Division of Organ Transplantation (DOT) in HRSA is responsible for montoring performance of the contracts for the OPTN and the Scientific Registry of transplant recipients. Both of these contracts are currently awarded to UNOS. In conjunction with HRSA's Contracting Office, staff of DOT closely monitor the performance of UNOS under these contracts through review of numerous contract deliverables, attendance at UNOS Board of Directors and committee meetings, and frequent contact with UNOS staff.

HEAL PROGRAM

Question. In Fiscal Year 1990, we appropriated funds to cover a shortfall in the HEAL program due to student defaults. No funds are requested for FY 91 for the HEAL student loan insurance fund.

Do you expect defaults to decline?

Answer: No, we do not expect that default rates will change significantly, although the litigation process may have a positive effect on the default rate. With increasing loans in repayment status even a stable default rate 8 percent will result in a significant increase in the dollar level of claims.

NATIONAL HEALTH SERVICE CORPS (NHSC)

Question. I received a letter from a State Health Officer who is concerned that, while National Health Service Corps doctors are supposed to be available to serve in county health departments, in fact all the Corps doctors are being assigned to community health centers. The Officer writes that placement of Corps personnel should be equitable among all public entities.

Please respond to these concerns, and provide the Subcommittee with detailed information on the placement of NHSC physicians in county health departments and freestanding (non-CHC) sites.

Answer. The Bureau of Health Care Delivery and Assistance and the National Health Service Corps (NHSC) have long targeted obligated providers to programs that are a part of an organized system of care serving a HMSA population. This policy has lead to the placement of a number of physicians in community and migrant health centers, both Federally and non-Federally supported.

County health departments may submit requests for the assignment of NHSC scholarship obligors. However, many of their positions are heavily involved in administration and research. A request from a county health department in the State of Georgia was not approved because the position was not for a full-time clinical practitioner. Obligated physicians must provide full-time primary care health services in high priority HMSAs. They are targeted for service to areas with high infant mortality rates and extreme poverty such as the inner cities.

There were 121 obligated scholars first available for placement in 1990. Of these, 31 have matched and 90 remain available for assignment. The remaining FY 1990 HPOL for obligated positions includes 135 positions allocated as follows:

Community and migrant health centers	44
Non C/MHC (PPO, PPS, freestanding sites)	9
Indian Health Service	69
Bureau of Prisons	13
Total	135

HANSEN'S DISEASE CENTER

Question. The budget proposes to cut 100 FTE from the Gillis W. Long Hansen's Disease Center at Carville, Louisiana.

What would be the impact of this proposal on patient care at Carville?

Answer. Our ability to provide both long term and acute care would be enhanced. The long term residential patients would continue to live at Carville as they have in the past. Acute care would be provided in the new leased facilities in Baton Rouge beginning in early 1991. Our ability to provide acute care would be enhanced by moving all clinical activity to Baton Rouge, except long term care of Hansens Disease resident patients at the Carville Campus. This move will enable the PHS to better utilize the modern facilities and non-HD specialties located in the Baton Rouge medical community. This arrangement will also enhance our ability to provide lifelong care to the current resident population of the Carville site.

Question. It is current contractor capable of providing care to all patients at the Center, or have other viable bids been received for providing contract health care services to Hansen's disease patients?

Answer. No contract for the care of all patients at Carville is currently in effect. Implementation of the strategic plan would require a contractor to assume such responsibilities. However, this may not be necessary. We are currently considering a proposal to enter into an interagency agreement with the Bureau of Prisons (BOP) to utilize excess space and services at the Carville site for minimum security, aged and psychiatric patients. The provision of services to BOP patients was not included in the original plan because it was not an option at that time. It has since become a viable option and we are in the process of discussing the details of an agreement under which BOP will gradually increase utilization of excess space and services at the Carville site. The services required by these patients will be similar to those required for the approximately 180 Hansens Disease patients now residing on the Carville site. If successfully concluded, this agreement will eliminate the need to reduce the number of positions at Carville from 300 to 200 and the plan to contract for services would also be dropped. The assumption by BOP of some of the surplus capacity and possibly some of the PHS employees at Carville would not affect the lifelong commitment to current residents. As before, the research, clinical services and training activities will be moved to leased facilities in Baton Rouge.

Question. What are the Administration's long term plans for Carville and for the Hansen's Disease program?

Answer. Consistent with the approved strategy, we will continue the Federal commitment for the Hansens Disease Program. With regard to the Carville site, we believe that this commitment can best be fulfilled by sharing the facility with another government agency in order to make the best use of the resources available and provide services most efficiently.

FRONTIER HEALTH CENTERS

Question. In 1989, the Department convened a work group on BCRR indicators, which are used to measure health centers' performance and grade them on their use of federal dollars.

Where is the committee's report on refining BCRR indicators?

Didn't the committee recommend that frontier health centers should receive a waiver from some requirements?

What is the status of the waiver: when will frontier centers be able to apply, and what will be necessary for getting a waiver?

Answer. The work group on performance measures has reported to the Bureau on refining the indicators used in assessing health center performance. During FY 1990 and 1991, the work group's recommendations will be incorporated into funding criteria.

No recommendation for a waiver of requirements for Frontier Centers was found in the Committee's reports.

All centers must continue to meet the requirements of the statute. Where performance measures go beyond statutory requirements, the Bureau policy is to be sensitive to local practice situations. This will assure that frontier centers are not disadvantaged. Formal waivers are not necessary.

CENTRALIZATION

Question. The concern has been raised that centralization of the process for making grants to community and migrant health centers has adversely impacted many of the smaller centers, and especially frontier centers. This is because the people reviewing their grant applications are not familiar with the rural areas, and don't visit the rural sites.

How many site visits will the Department make in FY 90 and FY 91, and which centers will be visited?

Answer. The people reviewing the grant applications are familiar with rural areas and do not visit rural sites. The centralized grant process involves three levels of review. First is the staff review by Regional Offices who are responsible for monitoring all centers including rural and frontier sites. The second level consists of an objective review conducted by Public Health Service Review Committees whose members, by design, are not from the applicant's Region or from Central Office units responsible for program management but who are knowledgeable program officials from other Regions. The third and last level of review is a staff summary of both sets of recommendations prior to decisions by the Bureau Director.

In FY 1989, 535 organizations were reviewed and received grant awards reflecting an annual funding level of $468 million. Approved applicants were categorized by the Bureau as Good (grade A or B), Satisfactory (grade C), or Poor (grade D or F). The results show that dollars follow results. Those grantees with a grade of A or B received 19 percent and 14 percent, respectively, over and above the FY 1988 base level. This compares to a 7 percent increase over base for grantees with a grade C, a 2 percent increase for those with a grade of D, and a 44 percent decrease for those with a grade of F.

When increases over the base level are compared for urban versus rural centers, rural received a $25 million (12 percent) increase over the FY 1988 base, while urban centers received a $20 million (9 percent) increase. This suggests urban C/MHCs are not receiving a disproportionate share of grant dollars.

It is BHCDA policy that if appropriate and sufficient resources are available, competing applicants (those at the end of their project period) should receive a multi-disciplinary site visit from Regional Office staff prior to preparing their grant applications. Noncompeting grantees may, if necessary and appropriate, also receive a site visit. In addition, following the grant review, all centers found to have serious operating problems receive a diagnostic site visit to determine whether and how the problems can be corrected. Estimated numbers of urban and rural centers to potentially receive each type of visit follow:

	Rural	Urban
Total	345	200
Competing visits	136	77
Non Competing	209	123
Serious problems	(34)	(17)

RURAL AND FRONTIER HEALTH CENTERS

Question. I'd like to get an accurate picture of the services provided through community and migrant health centers, including services to the homeless. The Department provides information on the number of patient encounters, but not the type -- a patient encounter could mean filling a prescription or stabilizing a heart attack victim.

Please provide the Subcommittee with information about the services centers are providing, and how services available at rural and urban health centers compare.

Answer. All community health centers are required to provide the following mandated services:

Primary health care services
Diagnostic laboratory services
Diagnostic x-ray services
Pharmacy services needed to complete treatment
Preventive health services
Preventive dental services
Emergency services
Transportation for patients who would otherwise lack access
Patient care management

These services must be provided directly by the grantee or through formal arrangements to ensure that all patients, including those without the ability to pay, have access. In addition to mandated services, grantees may provide supplemental services such as nutrition, health education, mental health and other health related services tailored to meet the specific needs of their communities.

The specific type of service provided to the patient is recorded in the patient's medical record. BHCDA reporting requirements require grantees to provide data on the number of medical and dental users. Encounters are reported by the categories of primary care, other medical, dental and other health. User and encounter data by type of supplemental service are not reported; however, staffing and dollars allocated to each of these cost centers is reported. This enables BHCDA to determine if funds are allocated for each mandated service and the appropriateness of the per user cost.

Medical services are comparable between urban and rural centers; however, urban centers tend to provide a greater level of supplemental and community services than most rural centers.

Homeless grantees are required to provide substance abuse services, which may include detoxification and residential treatment for substance abuse provided in settings other than hospitals; 24-hour emergency services; a system of referrals for mental health services; and a system for inpatient referral, outreach, and aid in establishing eligibility for and obtaining services under entitlement programs.

Question. I'm also concerned that counting the number of users served is biased against smaller centers, which have higher fixed costs. The health centers in Iowa don't serve the same number of patients as some health centers in New York or California, but they serve people who don't have other options. It's important to remember that.

How much of a factor in making grants is the geographic location of a health center, and what is the Department's policy on balancing grants by geographic region?

Answer. As you are aware, we have operated the C/MHC programs under a "no new start" policy for the past few years. As a result of this policy, our reviews have been of existing centers seeking continuation funding. All centers are evaluated by the following critical elements checklist:

- Need and community impact
- Management/Administration
- Clinical capacity
- Patient outcomes

Need and Community Impact - Although BHCDA programs are placed in poor and underserved areas, they must further document their service to the most needy persons in the communities they serve. This is accomplished by targeting populations with special needs such as migrant and seasonal farmworkers, women at risk for poor pregnancy outcomes, the homeless and persons with HIV illness.

BHCDA programs are designed to complement existing resources. In addition to providing services which would otherwise not be offered, BHCDA programs are required to build coalitions with other Public Health Service programs and with community medical, public health and social service providers. These linkages go beyond mutual referral arrangements; they increasingly involve the provision of other health and social services at the BHCDA grantee sites.

Management/Administration - BHCDA primary care programs are required to meet explicit and verifiable requirements for ongoing reporting of revenues and expenditures, financial viability, and process measures such as patient visits, other utilization data, and productivity of physicians and other health care providers. Beyond the reporting requirements, there are standards which must be met in each of these areas.

Clinical Capacity/Capability - Clinical capacity/capability refers to the basic structural elements of the program. This includes the number and type of full-time permanent physicians and mid-level practitioners. It also includes the training and qualifications of the individuals.

Because of the crisis faced by C/MHCs in recruiting physicians, particular emphasis is being placed this year on filling budgeted positions needed to operate the proposed program of each grantee.

If the positions are not filled by full-time permanent physicians within a certain number of months, funding will be reduced accordingly.

The ability to manage the patient's health care needs is also a high priority. Therefore, C/MHC physicians are required to have hospital privileges and to ensure continuity of care by following their patients in the hospital.

Finally, requirements pertaining to structural indicators include a quality assurance program, a detailed Health Care Plan, appropriate hours of operation and provisions for medical coverage when the site is closed.

Patient Outcomes - Outcome indicators on which BHCDA programs are evaluated are applied to the user population, but with increasing emphasis also on bringing in those community residents needing care in a timely fashion. At this stage, intermediate outcomes are examined - that is, the delivery of services in a manner expected to affect health status outcomes.

By using this combination of factors, we believe our review process allows for an equitable review of centers that is not biased against smaller centers in poor and underserved areas.

STATE LOAN REPAYMENT PROGRAM

Question. Last year, you testified that the State loan repayment program had not resulted in any contracts. As of last December, however, 57 physicians in seven states had entered this program. I understand that several other states have enacted legislation to support the state loan repayment program.

What is the budget request in FY 91 for this program, and how many contracts will that support?

Answer. The amount to be allocated for State loan repayments will be determined during the operating year (FY 1991) based on an assessment of the needs and opportunities at that time. In 1989, there were awards to seven States supporting 74 placements. Of these placements, none were to sites on the NHSC, HPOL or Loan Repayment vacancy list and 45 were used to retain practitioners in the positions they already held.

Question. How is the Department advertising this program?

Answer. State and territorial health departments were sent announcements and information concerning the program. In addition the program was announced in the Federal Register.

ACCESS TO CARE

Question. How does the Department measure how well the community health center programs provides access to care: how are the numbers of patients served balanced with the geographic location of the patients?

Answer. BHCDA programs are placed in poor and underserved areas, and grantees must document that their services are provided to the most needy persons in the communities they serve. As previously indicated, the Critical Elements Checklist used to evaluate grantee performance compares the profile of users with the service area data, e.g., the proportion of users with incomes below the Federal poverty level should equal or exceed the proportion of the service areas population under poverty. Within the overall underserved population, we also look at the grantee's performance in meeting the special health needs of population groups such as migrant and seasonal farmworkers, the homeless, HIV-infected persons, drug abusers and the elderly.

NATIONAL PRACTITIONER DATA BANK

Question. The National Practitioner Data Bank proposed to be completely funded through user fees in FY 91.

How much money did the data bank generate in FY 89, and how much did it cost to run?

Answer: The Bank is scheduled to open on April 2, 1990 and will begin to collect user fees at that time. The bank was not operational in FY 1989, and therefore no user fees were generated. The obligations incurred for the Bank in FY 1989 were $2,760,962.

NATIONAL HEALTH SERVICE CORPS

Question. What have recent program evaluations indicated about the effectiveness of the NHSC programs? How will the evidence from NHSC program evaluations change the recruiting strategies of the programs?

Answer. There are no recent formal evaluations concerning the effectiveness of the NHSC program. The basic recruitment strategy is to use the loan repayment mechanisms, State and Federal, to best serve the underserved in systems of care by placing practitioners in the approved sites. The loan repayment programs offer the advantage of almost immediate service and are likely to experience a lower rate of default. To the extent that loan repayment programs are not able to recruit sufficient numbers of practitioners for the highest priority sites, the scholarship mechanism will be employed. This mechanism is a proven provider of large numbers of practitioners for service in the hardest to fill remote rural areas and undesirable urban sites. The determination regarding which of the above mechanisms to employ will be made during the operating fiscal year based on assessment of the needs and opportunities the program is faced with at the time. This continued flexibility is critical to utilizing the available funds most effectively.

Question. What are the default rates of service obligations for both the loan repayment and scholarship programs? How effective are the programs collection efforts in recovering the amounts owed the federal government following a default?

Answer. In the history of the scholarship program, over 96 percent have fulfilled their obligation either through service or financial payback. The Government has been very effective in collecting the amounts owed as evidenced by the compliance rate. Because of the treble damages that the Government is now entitled to receive and the Government's aggressive approach in collecting amounts owed, fewer and fewer obligors are refusing to serve. In those instances when the Government has needed to go to court to collect, it has prevailed over 99 percent of the time. At this time no data are available concerning the default rates for loan repayment. Because the obligation to serve and actual service begin almost simultaneously and after the obligor's medical education is complete, it is expected that the propensity for default would be even less.

MATERNAL AND CHILD HEALTH (MCH)

Question. To what extent will States need to change their activities under the MCH block grant program to comply with the new application and reporting requirements enacted by the Omnibus Budget Reconciliation Act (OBRA) of 1989?

Answer. The OBRA of 1989 contains significant quantitative and qualitative changes for the States in both application and reporting requirements. Most States will, therefore, need to change several practices, such as the annual submission of a report of intended expenditures (RIE), which since 1981 have become customary in qualifying for continued funding under the antecedent MCH block grant program.

While plans for the implementation of all of the new requirements are still not final, it is likely that the activities of several States will have to undergo substantial revision to meet the new legislative requirements. For example, beginning with the 1991 application, which is due in the Office of Maternal and Child Health by August 15, 1990, States will have to make their MCH plans and activities consistent with the Public Health Service Year 2000 objectives. Another example is that States will have to prepare applications which indicate that they will spend at least 30 percent of their Federal funds on primary care and prevention, another 30 percent on services for children with special health care needs, and not spend more than 10 percent on administration. Also, States will be required to submit detailed needs assessments and show how their plans and activities will address these needs.

Guidance to the States on compliance with the new application and reporting requirements should be issued by the Health Resources and Services Administration within the next few weeks. In addition to the guidance, both regional and central office personnel of the Office of Maternal and Child Health will be meeting with State officials in Washington, D.C., in the regions and on site in the States to provide technical assistance on the application and reporting requirements.

Question. What is the Department doing to increase the available of obstetric and pediatric services, as required by OBRA '89? How will those efforts be coordinated with activities of the Medicaid program at the national, state, or local levels?

Answer. The Health Resources and Services Administration (HRSA) has begun planning for the complete implementation of OBRA '89, including those provisions relating to cooperation with the Health Care Financing Administration (HCFA), the agency which administers the Medicaid program. A definitive delineation of roles and responsibilities has not been completed. However, it is anticipated that the Maternal and Child Health - Medicaid Technical Advisory Group supported by the Office of Maternal and Child Health (MCH) and HCFA will continue to serve as a mechanism for improving the coordination between these two programs.

In recent years, the (OMCH) has implemented several programs and initiatives to increase and expand the availability of obstetric and pediatric services.

In cooperation with State programs, the OMCH has provided consultation and technical assistance for local communities attempting to coordinate and share resources to develop a comprehensive perinatal care system. Such systems utilize existing resources more effectively, assuring more women access to care, and often involve private practitioners. Recent examples include efforts in Vermont, Oklahoma, Indiana and Missouri.

A number of activities are being supported under the Title V Special Projects of Regional and National Significance (SPRANS). Through a cooperative agreement, the American College of Obstetricians and Gynecologists (ACOG), OMCH and HCFA are co-sponsoring a project to promote increased provider participation, especially by OB/GYNs, in publicly supported perinatal programs such as maternal and child health (Title V, SSA) and Medicaid (Title XIX, SSA). This program builds upon the recently developed effort between HCFA and HRSA to ensure that Medicaid programs address infant mortality issues to the fullest extent possible.

With the American Academy of Pediatrics (AAP), the OMCH has developed and implemented the Healthy Tomorrows Partnership for Children, a cooperative program to support preventive health projects for children under the direction of local community groups. The initiative encourages additional support from the private sector, from foundations and other community based groups to form partnerships to coordinate resources and services for pregnant women, infants and children.

With the National Governors' Association (NGA), OMCH has collaborated in presenting and disseminating information on ways to expand the number and type of providers through two recent publications, "Increasing Provider Participation" and "Enhancing the Scope of Prenatal Services."

Another possibility for increasing service providers exists under the new legislation. Under OBRA '89, when appropriations exceed $600 million, 12.75 percent of the excess - about $12 million - can be used for six new kinds of discretionary projects. One of these new priority areas focuses on activities to increase the numbers of private OB/GYNs and pediatricians in both Title V and Title XIX.

Question. What kinds of problems and programs will be the focus of the Special Projects of Regional and National Significance (SPRANS) in FY 91?

Answer. Due to our established practice keeping these projects as current as possible and to respond to emerging needs determined by practitioners and administrators in the field, we are unable to state with any degree of certainty at this time what specific problems these programs will address in fiscal year 1991.

Each year the Office of Maternal and Child Health performs a detailed analysis of current State, regional and national problems and issues in the fields of maternal and child health to determine the needs and funding priorities for research, training, hemophilia, genetic screening and MCH special improvement projects to be supported that year. Each State and all ten Federal regional offices are asked to submit individual lists of funding priorities. Based on this input, OMCH develops its SPRANS funding plan for the year.

It is anticipated that there will continue to be national concern about and that SPRANS projects will address such deep-rooted problems as the following: infant mortality; drug, alcohol and tobacco use; access to quality prenatal care; prevention of low birthweight; availability of providers and financing of care; nutrition during pregnancy and lactation; early childhood health; teen pregnancy; insurance coverage issues; services for chronically ill children; injury prevention; and family centered, community based, culturally sensitive, coordinated services and case management for children with special health care needs.

Question. What kinds of projects will be considered for providing health insurance coverage for uninsurable children when funds become available for these projects, authorized by OBRA89?

Answer. As mentioned previously, exact plans for OMCH special projects are not finalized until the fiscal year during which funds become available. That is also the case with this new provision of OBRA '89. We are currently in a discussion and planning mode at this time.

The section of the OBRA which authorizes up to four demonstration projects to provide health insurance coverage through an eligible plan to medically uninsurable children under age 19 has attracted considerable attention and will continue to merit study and analysis.

Any project funded under this provision will certainly meet all of the requirements specified in the law. That is, the projects will fund eligible health insurance plans which are school-based, under not-for profit entities and operated by not-for-profit hospitals. Such insurance will be made available for at least two years, incorporate a sliding scale of Federal matching and shall not restrict coverage based on conditions or impose waiting periods.

BHCDA CONTRACTS

Question. Please provide the Subcommittee with a detailed accounting of contracts the Bureau has made for FY 90, FY 89, and FY 88.

Answer. For FY 1988 and 1989 funding for contracts in the community and migrant health programs were as follows:

	1988	1989
Contracts:		
CHCs:		
Technical Assistance to CHCs	$150,000	$159,961
National Clearinghouse for Primary Care Information	130,000	179,517
MHCs:		
Interagency agreement with Health Care Financing Administration to finance hospitalization services	1,493,000	1,830,000

Amounts for 1990 are not available at this time.

Question. Please provide the Subcommittee with a list of regional and state primary care associations, their funding allocations for FY 90 and the last two fiscal years, and their current funding cycles.

Answer. The information follows:

	FY 1988 P.C. Assoc.		FY 1989 P.C.
Assoc.			
	State	Regional	State
Regional			
Region I		$117,362	
$110,350			
Conn.			$66,700
Me.	$147,567		136,018
Mass.	229,656		213,966
R.I.	30,000		62,500
Region II			
N.J.			106,395
N.Y	245,000		212,050
P.R.			77,136

	FY 1988 P.C. Assoc.		FY 1989 P.C.	
Region III		162,703		
189,703				
Pa.	242,644		158,087	
Va.	133,370		218,598	
W. Va.	110,000		154,550	
Region IV				
Ala.	115,000		140,665	
Fla.	154,500		20[illegible],900	
Ga.	100,000		100,000	
Ky.	40,888		67,350	
Miss.	27,500		158,850	
N.C.	154,300		174,920	
S.C.	162,400		103,106	
Tenn.	99,723		149,200	
Region V				
Ill.	100,000		103,500	
Ind.	64,194		79,738	
Mich.	100,690		104,214	
Minn.	42,029		46,098	
Oh.	118,990		98,990	
Wisc.	119,000		119,000	
Region VI				
Ark.	70,000		70,000	
La.	93,882		93,882	
N.M.	88,000		92,220	
Tx.	149,759		169,308	
Assoc.				
	State	Regional	State	Regional
Region VII			76,873	
Mo.	104,950			
Region VIII	237,265		259,850	
Region IX				
Ariz.	164,184		164,184	
Ca.	50,000		193,920	
Region X		223,200		354,350

- Amounts for FY 1990 are not available.

CONTRACTS WITH PRIVATE ORGANIZATIONS

Question. As part of the HRSA mission to promote primary care, the Bureau of Health Care Delivery and Assistance provides funds to State primary care associations. These groups work to coordinate local primary care services, and help to recruit doctors and other health professions to manpower shortage areas.

I have a newsletter from a private association here. It says that the Bureau of Health Care Delivery and Assistance has made a deal with this association to give financial support only to state primary care systems that operate through this private association.

What are the Bureau's plans for funding state primary care systems?

Answer. BHCDA does not have an exclusive arrangement with any private association. BHCDA has traditionally worked with a number of national organizations who represent members involved in the provision of health and social services to high-risk and underserved population groups. To this end, BHCDA has relationships with the National Association of Community Health Centers and a wide variety of constituency groups, including the National Rural Health Association, the National Governors Association, the National Association of County Health Officials, the Association of State and Territorial Health Officers and the National Conference of Mayors. Decisions about funding State and Regional Primary Care Associations (S/RPCSa) are made through the same three step review process applied to all BHCDA grantees:

1. Staff review by Regional Offices.

2. Objective review by Public Health Service Review Committees whose members are not from the applicant's Region or from the Central office units responsible for program management.

3. Staff summary of both sets recommendations prior to decisions by the Bureau Director.

Applicants are judged according to predetermined criteria regarding their degree of representation, financial accountability and substantive activities. There is no requirement that they operate through any national organization; indeed they must be independent private non-profit corporations. S/RPCAs are encouraged to coordinate their activities with the types of national organizations described earlier.

Question. Up to now, these primary care associations have been funded on a three-year cycle; but now they are being funded only through the end of this year.

What is the rationale for the new funding cycle?

Answer. S/RPCAs have always and will continue to be funded with one year budget periods. When administered by regions, project periods were not uniform. Since 1986, BHCDA's policy has been to award coterminous one year project and budget periods. However, due to the three year project periods of awards made during Regional office administration, 8 of the 35 projects have project periods ending September 31, 1991. Subsequent fundings of S/RPCAs will also be for one year budget and project periods.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

NATIONAL HEALTH SERVICE CORPS

AMERICAN SAMOANS, HAWAIIANS, AND PACIFIC BASIN

Question. Secretary Sullivan has supported the funding of the National health Service Corps with focus on getting disadvantaged and minority students and training them to return to their communities; furthermore, he is to be recognized for the funding recommendation for the disadvantaged and minority students and health professions schools in order to increase the representation of minority health practitioners, who are more likely to practice in minority communities where health status is low; thus, based on this very philosophy I recommend funding for an initiative that trains disadvantaged minority students - American Samoans, Hawaiians, Pacific Basin -from areas with an enormous and clearly documented need to return to their community and provide health care.

Answer. No funds in the budget request are targeted specifically for health professions students in American Samoa or the Pacific Basin. However, under the National Health Service Corps, funds are requested for the minority health program under which American Samoans or other minority residents of the Pacific Basin may qualify. In addition, scholarship funding for Native Hawaiians under the Native Hawaiian Health Care program is requested.

Nursing

Question. The National Health Service Corp administration budget recommends that monies made available for FY 89, be directed to fill 250 physician slots with the highest priority given to obstetrician and family practice physicians. Last year the Appropriation Committee recommended $3 million of the $8 million provided for loan repayment and scholarships be targeted to nurses. However, of the 240 slots for identified for physicians only 30 were identified for nurses. Clear 30 slots do not utilize 3 million dollars, thus one can only assume the NHSC is continuing to proceed the traditional recommendations. Can you explain this decision?

Answer. The Federal loan repayment program offers contracts for approved commercial or government health professions education loans in exchange for service to those qualified individuals who are completing their training. In FY 1989, there were 197 qualified physicians and nurse applicants for the NHSC loan repayment program. Only 28 of these applicants were nurses, two fewer than the number of slots identified for 1990. Of these 28 applicants, 15 were matched to sites. The problem in placing nurses in underserved areas remains one of attracting nurses to the program, not an insufficient allocation of the slots for which the government recruits or the resources available for nurse loan repayment.

Question. It is understood when the NHSC began the emphasis was with regard to physicians, however, current studies clearly show the midlevel (Nurse Practitioner, Physician Assistant and the Certified, Nurse Midwife) provides 75-80 percent of primary care. Of the care provided studies show that care provided is better, especially in the care of chronic illness, which is primarily comprised of the elderly. Furthermore, the research shows the Nurse Practitioner has the greatest effect on the health promotion and disease prevention issues. Issues I might add which plague the underserved and disadvantaged areas. Given these studies, the cost of training a mid-level practitioner, and the speed in which these individuals can be prepared to begin practice couldn't some of these physician slots be priorities for mid-level practitioners.

Answer. The lower cost of training a nurse or mid level practitioner is one of the reasons that a loan repayment program for such individuals has difficulty in attracting applicants. Nurses generally do not attain the degree of indebtedness that physicians do because both the cost of nurses education and the earning potential of nurses, which determine need and ability to repay, are generally less. With this generally lower level of debt, a loan repayment program is not as likely to attract nurses as it is physicians to the remote and difficult to staff sites for which the National Health Service Corps recruiting.

Question. Dr. Wagner, Pediatrician and head of the World Health Association stated to the U.S. Commission to Prevent Infant Mortality, that in every single European country who uses midlevel Certified Nurse Midwives they have a significant lower infant mortality rate. In fact these countries have a much greater ratio of CNM to that of OBI Physicians. Again, wouldn't it be prudent and cost effective to fill some of those physician slots with CNM?

The policy of the NHSC is to assure health care in the disadvantage and undeserved areas it seems the time is now for the priority to be reassessed and emphasis nursing and midlevel providers.

Answer. The primary difficulty facing the NHSC remains that of attracting these providers to the program through the mechanisms the NHSC employs.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

HEALTH PROFESSIONS TRAINING PROGRAM

Question: The FY 1991 budget proposes to eliminate virtually all funding for Health Professions Training programs. What evidence does HRSA have that Federal assistance for these programs are no longer needed?

Answer: In order to meet mandated deficit reduction goals and budget targets for the FY 1991 health programs, very difficult choices among priorities for Federal funds must be made.

In FY 1991 BHPr will focus our health professions support on programs designed to assist minority and disadvantaged students. These programs include: exceptional financial need scholarships; the excellence in minority health program; the financial assistance for disadvantaged students program; and the health careers opportunity grant program.

Question: How much did HRSA request for Health Professions Training programs in its FY 1991 budget submission to the Public Health Service?

Answer: The HRSA FY 1991 request was $248,250,000 for Health Profession Training and Nurse Training programs. In addition, HRSA requested $3,000,000 for the National Practitioners Data Bank, $1,360,000 Ad Hoc Hospitals, and $44,800,000 for the HEAL/SLIF account.

AIDS HOME HEALTH GRANT PROGRAM

Question. The FY'91 budget proposes to eliminate funding for demonstration grants to States to encourage the development of home and community-based health services for persons with AIDS. Given the recent projections of the cost of caring for AIDS victims, what is the justification for eliminating funding for this program?

Answer. THe intent of the formula grants to States for Home and Community-Based Services is to encourage the development and provision of home and community-based services to the States and Territories. No funds were requested for FY 1991 because the authorization for the program expires at the end of FY 1990. Also, the need for this kind of program is being met to some extent in certain metropolitan areas by the HIV Servile Demonstration Program, which supports the development of local case-managed systems of HIV care that include home health services along with other medical and social support services.

RURAL HEALTH

Question. Senator Cochran is introducing a bill, after the February recess, which provides federal matching grants for the creation and enhancement of State Offices of Rural Health to help coordinate and improve rural health care delivery.

Do you see the need for such offices?

Answer. Senator, we have been very impressed with the work of many state offices of rural health. They have provided a voice for rural constituencies within state capitals. They have provided valuable technical assistance to local communities trying to solve problems ranging from recruiting physicians to keeping their hospitals open. They often run state programs that provide health services or information to rural areas. Our Federal Office of Rural Health Policy plans to bring the state offices together this summer for a workshop in which they care learn from each other.

QUESTIONS SUBMITTED BY SENATOR PETE V. DOMENICI

COMMUNITY HEALTH CENTERS

Question. What is HRSA's policy when they receive funding for new initiatives? Do you limit eligibility to community and migrant health centers that are already grantees?

Answer. Although HRSA's service delivery programs are placed in poor and underserved areas, they must further document their service to the most needy persons in the communities they serve. This is accomplished by targeting populations below the Federal poverty level, racial and ethnic minority groups, and populations with special needs such as migrant and seasonal farm workers, women at risk for poor pregnancy outcomes, the homeless and persons with HIV illness. For example, the perinatal program funds are distributed according to infant mortality rates, which may be adjusted to apply to a particular area or population targeted. NHSC physician placements are made according to documented need and unsuccessful efforts to recruit privately, the existence of a fiscally sound community-based organization, community support, and assurances that person will be served regardless of ability to pay. Using these criteria, recipients of HRSA special initiative funding are, in most but not all cases, existing community and migrant health centers. The following is a description of the special initiatives that provide additional funding for HRSA's service delivery programs:

> The comprehensive perinatal initiative provided $20 million in both 1988 and 1989 for maternal and infant care. The funds were appropriated under the Migrant Health Center and Community Health Center authorities (Sections 329 and 330 of the PHS Act) and were therefore restricted to these programs.
>
> The Health Care for the Homeless Program originally supported 109 community-based organizations of which 55 were community health centers.
>
> The substance abuse initiative funded under a reimbursable agreement with the Alcohol, Drug Abuse, and Mental Health Administration provided funds to 21 community-based organizations of which nine were community health centers.
>
> Funding for AIDS prevention and treatment programs provided under a reimbursable agreement with the Centers for Disease Control supported three community health centers as pilot projects. In 1990, with over $10 million available to expand the program, as many as 20 centers will be supported.

Question. Have there been problems as you have moved to the centralized operation of the community/migrant health service program? Are national standards appropriate in all regions of the country? Do community and migrant health centers typically provide the same type of service in different regions of the country.

Answer. There have been no significant problems as a result of the conversion to the centralized system of making grant awards for community and migrant health centers, and the new system has many advantages to the grantees and the population being served as well as to the management of the program.

Some national standards are indeed applicable throughout the country, particularly with respect to statutory requirements, quality of care, and business management practices.

All community and migrant health centers are required to provide an array of services regardless of where they are located. However, urban centers tend to provide a greater level of supplemental and community services than do most rural centers.

Question. Please describe the rating system for community health centers.

Answer. Grant reviews result in an assessment of the quality of the health care delivery program in terms of structural, procedural and intermediate outcome expectations. Applications are reviewed initially by regional office program and grants management staff. Subsequently, Public Health Service Review Committees (PHSRC), comprised primarily of staff from regions other than those in which the grant applicants are located, review the applications and make recommendations. Next, central office staff review the applications and both central office and regional office staff comment on the PHSRC recommendations. Finally, the Bureau Director reviews all the materials and makes a final decision. Grantees may request reconsideration on the decision of the funding level.

NATIONAL HEALTH SERVICE CORPS IN THE NEW MINORITY HEALTH INITIATIVE

Question. You have asked Congress to expand funding for the National Health Service Corps (NHSC). This may help frontier areas having more difficulty than ever recruiting medical personnel. For example, La Clinica del Pueblo in Tierra Amarilla, New Mexico is the only health care facility in an 250 square mile frontier area. By May, unless some medical personnel are recruited, this facility will have to close, at least partially, due to lack of personnel.

Will rural and frontier communities be prioritized for placement of NHSC personnel?

Answer. In 1989, 17 million Americans live in underserved urban areas and 16 million live in underserved rural areas. There are 1,955 primary care shortage areas with a total need of over 4,200 primary care physicians.

In order to place NHSC obligors throughout the country the NHSC uses the High Priority Opportunity List (HPOL). The criteria for inclusion on the list are:

1. The system of care must be in a HMSA.

2. There must be documented health care need based on physician shortages, high infant mortality, high poverty levels and lack of access to health services.

3. There must be a documented non-availability of health care services resources in contiguous areas.

4. There must be an effective community based organization either existent or in development which demonstrates the capacity to meet the needs of the unserved, underserved, and/or minority populations.

5. There is documented information that active recruitment efforts have been undertaken and have failed.

6. There is documentation that the lack of placement at the site will have a significant negative impact on the delivery capacity of the total system of care, including consideration of loss of services and/or possible site closure if the position is not filled.

7. There is a documented record of sound fiscal management of the applicant.

8. There is general community support of the placement of NHSC members in the community.

9. There is documentation that the NHSC member will be located so that the member will provide services to the greatest number of unserved, underserved, and/or minority persons residing in such area.

Sites which meet these criteria are most likely to be included on the HPOL and be assigned a NHSC physician.

Question. Is the NHSC aware of some of the special problems facing frontier areas in rural New Mexico and other parts of the country? Can any special effort be made for facilities that are the only health facility in such a large geographic area?

Answer. The program uses the criteria just described in selecting the sites for which it will recruit. If the areas to which you refer meet those criteria, it is likely that appropriately operated sites would be included on the HPOL.

HEALTH CARE FOR THE HOMELESS

Question. Your justification request indicates that the FY 1991 Budget request for health care for the homeless of $33.7 million will fund 92 projects for 9 months. You have requested no funding for the first quarter of FY 1992.

Does the budget assume sufficient funding in FY 1992 to fund all 92 of these projects at the 1991 level or more?

Answer. The President's FY 1992 budget request has not yet been developed.

Question. What is the specific funding assumption for FY 1992 in this Budget?

Answer. There is no funding assumption for fiscal year 1992 since the President's fiscal year 1992 request has not been developed.

Question. Will 9 month grants be necessary as a result of this request? Will this disrupt operations of the health care for the homeless projects?

Answer. In December 1989 awards were made for the period January 1 through September 30, 1990. On October 1, 1990, supplemental awards will be made for the period October 1 through December 31. At the end of December, new awards will be made for the period January 1 through September 30, 1991.

SUBCOMMITTEE RECESS

Senator HARKIN. Thank you very much. The subcommittee will stand in recess until 10 a.m., Tuesday, February 20, when we will meet in SD–138 to hear from the National Institutes of Health under the jurisdiction of the subcommittee.

[Whereupon, at 12:36 p.m., Friday, February 9, the subcommittee was recessed, to reconvene at 10 a.m., Tuesday, February 20.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1991

TUESDAY, FEBRUARY 20, 1990

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met, at 10 a.m., in room SD-138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Bumpers, and Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF WILLIAM F. RAUB, ACTING DIRECTOR

ACCOMPANIED BY:

- KATHERINE L. BICK, DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH
- JOHN D. MAHONEY, ASSOCIATE DIRECTOR FOR ADMINISTRATION
- NORMAN D. MANSFIELD, ASSOCIATE DIRECTOR FOR RESEARCH SERVICES
- LEAMON M. LEE, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT
- ANTHONY S. FAUCI, ASSOCIATE DIRECTOR FOR AIDS RESEARCH
- DENNIS WILLIAMS, OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator HARKIN. Good morning. The Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will come to order.

This morning and in our session this afternoon the committee will consider the fiscal year 1991 budget request to the National Institutes of Health of $7.93 billion, which is $354 million or 4.7 percent over last year's level.

I have been told the biomedical inflation rate is projected to be approximately 5.8 percent. In other words, the administration's budget request for NIH does not keep up with inflation. And I am sure this committee will want to make every effort to at least ensure that the NIH funding keeps pace with inflation—I say that at least at a minimum.

This budget proposal does, however, include a number of features that do deserve support. I was pleased to see that the total number of research project grants of 20,439 and new grants totaling 5,095 were both increased in fiscal year 1991 over the levels that existed last year.

Every meeting I have, Dr. Raub, with the biomedical research community includes a discussion of the declining percentages of the approved grants that are funded. I understand that the 1989 level was 29.4 percent. It is estimated to decrease to 24.2 percent in 1990.

I was pleased to see in the budget request, however, that the estimated percentage of approved grants that will be funded in the President's budget would increase to 25 percent. We would all like to see a higher percentage of approved grants being funded each year. It is, therefore, good news to see the percentage move up in fiscal year 1991.

I should note, however, that there appears to be a number of underlying factors completely within the control of NIH that resulted in the decline in the number of approved grants that are funded.

One such factor—and some of these I want to cover in the questions and answers and you might want to address them in your statement—is the approval rate for grant applications. In 1989 NIH approved 95 percent of the grant proposals that were submitted.

These approved grants were indicated to be meritorious and worthy of funding. That is in 1989, 95 percent. In fiscal year 1982 only 85 percent of the grant proposals submitted were approved. I would like to know why is this happening.

As NIH chooses to approve an ever-increasing percentage of grants, it only follows that a smaller percentage will be funded.

Another factor that contributed to the decline in the percentage of funded approved grants is that NIH lengthened the time period for grant funding. In 1989 the average length of the grant was 4.2 years. In 1981 it was 3.3 years. Again, I would like to know why this is also happening.

Again, I am not necessarily quarreling with either one of these trends, but I just need to understand them. And I think members of the committee need to understand why this is happening.

Needless to say, we could overcome these trends with large increases of funds every year and that may be your response. And each year we do try to provide additional funding.

I would point out that the NIH budget has doubled since 1980, happening during a time when discretionary spending has essentially been flat in other programs under this subcommittee's jurisdiction.

Since I entered Congress in 1974, the NIH budget has increased from $1.9 billion to $7.9 billion. So I think this indicates that Congress and the American people do have confidence and respect for the outstanding and important work of the National Institutes of Health.

Today we will hear about the biomedical research challenges and opportunities that we face from all of the different Institutes' centers.

And Dr. Raub, I would, in just closing my remarks, like to say a few words to you personally. Since last August when you were named the Acting Director of the National Institutes of Health, I have noticed the steady course and fine stewardship that you have provided in this interim period. I want you to know that I and all of my colleagues join me in expressing our appreciation to you for the fine leadership that you have provided during this interim period.

Again, Dr. Raub, welcome to the subcommittee. And likewise I would like to welcome all of the Institute and Center Directors who I see are here. Again, we appreciate all of your fine work, and we look forward to hearing your statement either during this morning's session or this afternoon's session.

At this point I would like to leave the record open for any opening statement or comments by Senator Specter and any other statements by members of the subcommittee.

PREPARED STATEMENT

Senator HARKIN. Dr. Raub, again, welcome and thank you for your fine work and your leadership at the National Institutes of Health. And please proceed as you so desire. Your complete statement will be included in the record.

[The statement follows:]

STATEMENT OF WILLIAM F. RAUB

Mr. Chairman, it is my privilege to appear before you and your colleagues on the Subcommittee to present the President's fiscal year 1991 budget proposal for the National Institutes of Health. In my presentation I will describe some of the advances made during the past year, discuss briefly a few significant new programs, mention some current issues, and outline the key points of the fiscal year 1991 budget proposal.

In subsequent testimony Directors of our constituent units will describe in detail a number of important accomplishments, but I will take the liberty now of citing briefly a few highlights. For example:

—Last year, a team from the National Cancer Institute (NCI) and the National Heart, Lung, and Blood Institute (NHLBI) transferred cells containing foreign genes into humans for the first time. This successful use of a tracer gene not only is the first application of a powerful new tool for research but also constitutes a major step toward gene therapy in humans.

—Scientists at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) have determined the structure of the receptor, a protein on the surface of most cells and basal cells that plays a central role in allergic reactions. From this information the scientists have developed a tissue culture system that can be used to screen for a new class of drugs, possibly for the prevention of allergy attacks.

—Grantees of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and of NHLBI have isolated the cystic fibrosis (CF) gene. This step enhances significantly the prospects for developing drugs that can be designed to correct the defect.

—Polymerase chain reaction (PCR), a powerful new technique developed directly from basic research funded by NIH, is now used in many areas of research and service. It is expected to have a profound effect on the joint effort by the NIH and the Department of Energy (DOE) to map and sequence the genome of humans and other organisms. PCR is the cornerstone of a proposal to "translate" the information from various physical mapping methods into a common language known as sequence-tagged-sites (STS). These sites are short tracts of a unique DNA sequence that can be identified by PCR and that can act as landmarks on a physical map.

During 1989 the NIH continued to lead the Federal Government's research efforts against AIDS through studies conducted by our intramural scientists, by grantees, and by contractors. Studies sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) have shown that the drug AZT can delay disease progression in HIV-infected persons with low counts of T4 cells whether they have AIDS symptoms or not. These studies indicate that an estimated 600,000 HIV-infected Americans with early or no symptoms of the disease could benefit from AZT treatment. Another study has shown that reduced dosages of AZT are effective and reduce side effects. The efficacy and toxicity of a promising new drug, dideoxyinosine (ddI), will soon be compared with AZT in a large study.

The NIAID has established 18 AIDS treatment research programs based in the communities where people with AIDS live and receive their medical care. The program will reach increased numbers of persons with HIV infection, including those in population groups that have been underrepresented in AIDS studies.

The accelerated pace and productivity of basic biomedical research, so characteristic of its recent history, continues unabated. There has been a marked shortening of the interval between new findings from basic studies and their widespread application in measures for improving the health of the American people.

The NIH intramural program is recognized as a leader among government agencies in implementing the Technology Transfer Act of 1986, whose purpose is to facilitate the transfer of the results of federally supported research through development and then through widespread use. The NIH now has about 100 Cooperative Research and Development Agreements (CRADA's) with industry and about that many more in various stages of negotiation. Through the CRADA's, government and industry scientists can make optimum use of the resources unique to each party in their joint research efforts.

The National Center for Biotechnology Information (NCBI), established at NIH in late 1988 within the National Library of Medicine, has begun to integrate existing data bases and is developing new computer programs to analyze them. Information access has become an urgent problem, not only for the human genome program, but also for the many facets of biotechnology.

While we extend our efforts in technology transfer, we must ensure that research goals are not unduly influenced by conflicts of interest affecting the participants in research projects at awardee institutions. We seek balanced solutions that will protect the integrity of the supported research without imposing unnecessary restrictions on this creative enterprise.

We also face concerns about dishonest practices in biomedical science. Misconduct in science is rare, but when it occurs it undermines the public's faith and can jeopardize subsequent research and even proper medical treatment. To monitor and investigate all misconduct in science cases in the Public Health Service—which includes any on the NIH campus or at awardee institutions—the Office of Scientific Integrity (OSI) was established within the Office of the Director, NIH. It currently is dealing with 72 active cases. The OSI will collaborate with the Office of Scientific Integrity Review (OSIR) that recently was established in the Office of the Assistant Secretary for Health.

In another area of concern, I note with alarm the continuing attacks on biomedical science by advocates of animal rights. At a time when biomedical research is making such rapid progress and its benefits are ever more promising, it is tragic that animal "rights" activists continue to intensify their efforts to stifle important avenues of research through harassment of individual scientists and blatant terrorist acts of theft and property destruction. We at the NIH believe that the use of laboratory animals is a scientific necessity and, in fact, is an ethical imperative. We are greatly concerned about the humane care and use of animals and strongly believe that good animal care is an indispensable part of good science.

Mr. Chairman, the fiscal year 1991 budget request for the NIH is $7,929.7 million, an increase of $353.3 million or 4.7 percent over the comparable fiscal year 1990 level. The requested increase includes an additional $56.6 million for the AIDS program and $48.5 million for the Human Genome Initiative. The budget request continues to reflect the priority the Administration places on the support of basic research, seeking an increase of 5.7 percent.

In allocating the fiscal year 1991 request, NIH gave its highest priority to the support of improvements in its intramural facilities, whose needs have become critical in recent years. Of particular importance is continued support for ongoing modernization of the Warren Grant Magnuson Clinical Center, for renovation projects in our laboratory buildings and the upgrading of our animal facilities. Furthermore, the condition of NIH boilers, chillers, and steam lines has reached the critical point where the useful life of these vital facilities is ending. The NIH firmly believes that these needs must be addressed and has requested $88.6 million, an increase of $27.6 million over the 1990 funding level for the building and facilities fund.

Investigator-initiated research continues to be a very high priority. Research project grants would be funded at a level of $4,425 million, an increase of 5.4 percent over the 1990 funding level. This amount will allow average cost increases of about 5.8 percent for noncompeting and 2 percent for competing awards. The fiscal year 1991 request would support a total of 20,439 research project grants, of which 5,095 would be competing research project grants, an increase of 462 competing awards over the fiscal year 1990 level.

The NIH also continues to place a high priority on research training. The fiscal year 1991 request will support a total of 12,020 trainees, an increase of 225 over the fiscal year 1990 level.

As a reflection of the importance NIH places on expanding the number of biomedical researchers who are ethnic minorities, the fiscal year 1991 budget requests that the Minority Access to Research Careers Program, the Minority Biomedical Research Support Program, the Minority High School Apprenticeship Program, and the Research Centers in Minority Institutions receive an overall 17 percent increase over fiscal year 1990.

In fiscal year 1991 the Biomedical Research Support Grant Program will be funded at a level of $17.7 million. Consistent with the Secretary's minority health initiative, one-third of the 1991 funds will be awarded to institutions to increase support for underrepresented minorities or economically disadvanted students in science and engineering.

The Intramural Research Program at NIH constitutes the nation's preeminent institution for the biomedical sciences. The request for intramural research of $914.9 million provides an increase for intramural research of 6.9 percent over the fiscal year 1990 base. This increase allows for continuing expansion in the AIDS program and will cover the costs of such administrative items as within-grade increases and the costs associated with January, 1990 and 1991 pay raises.

The request also includes $20 million for the Director's Discretionary Fund. Although Congress did not support this fund in the fiscal year 1990 appropriations, NIH believes it is an important mechanism that will allow the NIH to be more responsive to emerging research opportunities.

For the first time, a separate request is made for the recently established new National Center for Human Genome Research, and it proposes a significant increase, continuing the emphasis placed on this initiative by the Administration. A five-year plan to be released in the spring of 1990 establishes the scientific goals for the U.S. human genome project from 1991 to 1995. The fiscal year 1991 request for the Center is $108 million, an increase of $48.5 million over the comparable fiscal year 1990 estimate. The successful completion of this project holds great promise for future advances in health research.

I would be pleased to respond to any questions you may have.

INTRODUCTION OF ASSOCIATES

Dr. RAUB. Thank you very much, Senator Harkin. My colleagues and I appreciate your support and, as always, are pleased to have this opportunity to tell you about our programs.

With me at the table today are Mr. Norman Mansfield, Associate Director for Research Services; Dr. Katherine Bick, Deputy Director for Extramural Research; Mr. John Mahoney, Associate Director for Administration; Dr. Leamon Lee, Director, Division of Financial Management; Dr. Anthony Fauci in his capacity as the NIH Associate Director for AIDS Research; and Mr. Dennis Williams, representing the Office of the Secretary, HHS.

I have a prepared statement, and with your permission, Mr. Chairman, I will submit it for the record and provide just a few highlights of it now.

Senator HARKIN. It will be made a part of the record in its entirety.

FISCAL YEAR 1991 BUDGET REQUEST

Dr. RAUB. Thank you, sir.

Our written justifications and the testimony you will be hearing later today emphasize many of the achievements of the last year.

In the interest of time, I will highlight only one area of significant progress, the progress against cystic fibrosis.

As you know this is a fatal disease, claiming its victims often in early childhood or as young adults. One of its major manifestations is a thick, copious mucus in the lungs producing constant difficulty in breathing and harboring bacteria that cause life-threatening infections. Cystic fibrosis is the most common genetic disease among Caucasians, with the defective gene occurring in 1 out of 20 Caucasians and the disease itself being manifest once in every 2,000 births.

Within the last year, the gene causing this abnormality has been found by grantees of the National Institute of Diabetes, Digestive, and Kidney Diseases and the National Heart, Lung, and Blood Institute. Those scientists also received important support from the Howard Hughes Medical Institute and the Cystic Fibrosis Foundation.

Since this gene was discovered, the pace of the research has been almost breathtaking. The gene has been sequenced and its protein product identified. It turns out to be a component of the cell membrane that is involved in the transport of chloride ions connected directed to the clinical manifestations of the disease.

This new insight has given important leads for the development and testing of inexpensive screening tests which will aid genetic counseling as well as new leads for therapies, especially drug therapies, that might block and one day prevent cystic fibrosis.

Similar scenarios are playing out across all of the programs of the NIH. With 4,000 known genetic diseases and others sure to be discovered, the prospects are bright indeed. Time and again we will see human disease reduced to the essentials of the gene sequence. The protein product, the abnormalities that occur, the structure and function of the components, and the direct relationship to the cause of disease will be identified leading to new means of prevention.

At the same time, clinical scientists are making progress against cystic fibrosis as well. Scientists funded by the National Heart, Lung, and Blood Institute demonstrated the efficacy of a drug that makes the lung sputum less viscous. This drug can be administered as an aerosol. It eases breathing and reduces the risk of infection, thereby decreasing the morbidity associated with the illness. It also has the prospect of increasing the lifespan further.

This may not be the level of blockbuster news that the discovery of the gene was, but it is the kind of incremental, steady advance on which so much of our progress depends. Similar examples of successful clinical trials and other clinical research in other areas abound in our testimony.

Taken together, they illustrate the balance in the NIH strategy, looking not only for investments that yield a payoff today or in the short term, but also investments that produce extraordinary promise for tomorrow.

Turning to the fiscal year 1991 request, I call your attention to several factors. Overall, the budget proposes to maintain a strong effort across a broad front: basic and targeted research, laboratory and clinical research.

In particular, the budget emphasizes basic research as is manifest in the proposed funding increases for research project grants and for intramural research.

The budget also proposes a strong continuing assault on AIDS, buoyed especially by the rapid scientific developments and the dramatic progress in the development of effective drug therapies.

The budget also calls for a major expansion in the human genome project and a significant expansion in our efforts to attract more minority and disadvantaged individuals into research careers. The minority programs cover a spectrum from high school to the postgraduate years.

The budget also gives major emphasis to repairing and refurbishing the buildings and facilities that serve the NIH intramural program.

Because buildings and facilities present us with our most urgent problems, this last item emerges as the most important one in this particular request. We are deeply concerned about the safety of patients and staff in our clinical center as well as the safety of scientists and support personnel in laboratories and related facilities. As the years go by, the difficulties of ensuring that safety become ever more formidable.

At the same time we struggle to avoid inefficiencies and costly shut downs associated with obsolete or overtaxed utility systems. We also are bent upon ensuring that our facilities for laboratory animals conform to the letter and spirit of applicable regulations and guidelines.

In addition, we want to ensure that our scientists are able to address the research needs and opportunities of the 1990's, many of which are beyond the capabilities of buildings and support systems dating from the 1940's and the 1950's.

As reported elsewhere, we expect to be grappling with the problems of our research infrastructure and physical plant for at least the next decade.

Mr. Chairman, we are living through a time of extraordinary progress and prospects for biomedical science. The NIH is privileged to be at the forefront of that enterprise, thanks to the strong, sustained support from a succession of Congresses and Presidents.

We are committed to seeing these investments continue to yield a high return in terms of new scientific knowledge and better health for people everywhere. On behalf of the National Institutes of Health, I present our request of $7,929,686,000 for fiscal year 1991. My colleagues and I will be pleased to respond as best we can to your questions.

HUMAN GENOME PROJECT

Senator **Harkin**. Dr. Raub, thank you very much for your statement.

Over the weekend I read most of the different testimonies. The story of the discovery of the gene on cystic fibrosis, how difficult it was to find and locate it and the pace that has taken place since that time, was really quite intriguing. This of course prompts me to say once again how important the whole study of the human genome is to so many illnesses.

I know there is an increase in here for the human genome project. How much is the total spending next year for that project? What is the increase in percentage terms?

Dr. Raub. Our request for the human genome project is $108 million for fiscal year 1991. This is an increase of 81 percent over the fiscal year 1990 level of $60 million.

Senator Harkin. What is the latest in terms of time frame for the mapping of the human genome? What do you see out there? How long is it going to take us to do this?

Dr. Raub. When the project began, scientists involved with it estimated that on the order of 10 to 15 years would be required to complete mapping and detailed sequencing of the so-called base pairs, the individual units of information that make up the genome. With 3 billion such pieces of information making up each one of us, the task was seen as that formidable.

The time line estimates necessarily change from year to year as new technology develops. For example, with the deliberate early emphasis on technology for sequencing in the genome project, there are revised estimates as to the cost of the sequencing. These estimates bring the cost down well below the $5 per base pair that originally was projected. There are also new laboratory techniques that make it possible to handle larger pieces of the chromosome. I have not seen that translate yet into a dramatically different estimate of the time line. Recognizing the difficulty of the task, however, I believe those close to it are optimistic that, as the technology improves, more and more rapid progress will come about in even more economical ways.

Senator Harkin. Well, I am led to believe that basically we know how to do it, but we need the computer facilities, the supercomputers and others. Plus we need the scientists to do the work.

In other words, this may be one case where front-loading on funds and money may in fact shorten the time period. Is that true or not?

Dr. Raub. I do not believe that would be materially true in the sense that, while we can do it, many of the techniques are labor-intensive. If we invest now in the development of those techniques, there is every reason to believe that automation will be able to make a major impact.

Senator Harkin. But if it is labor-intensive and you have more labor doing it, that shortens the time period.

Dr Raub. To some degree, that is true. However, there is also the associated problems of coordinating an effort of that magnitude and having the data systems available to receive and to make that information readily available to those working in the field. We are also making investments in those computer systems.

Senator Harkin. So if you have that and you have more labor working on it, it would seem to me you could shorten the timeframe.

Dr. Raub. I cannot argue that it could not be shortened. I think my major point is that it is not seen as a particularly efficacious investment to have a large number of highly trained people in some of the rote sequencing work, especially when it is so costly at its labor-intensive forms. Therefore, we believe a more balanced effort focused on improved technology development will pay off much more effectively in the long run.

Senator **Harkin**. I understand. Counsel is telling me that you want to get the price per bit or pair down. What did you mention it was right now?

Dr. **Raub**. Yes; when the project started the cost estimates were in the order of $5 per base pair. In recent years, it has dropped to about one-half that, and there is reason to believe that it can be reduced to the order of 50 cents per base pair with heavy dependence on automated techniques.

Senator **Harkin**. I am very interested in this project and from talking to a number of people, it has occurred to me that this 15-year timeframe that was initially viewed could be collapsed quite a bit with the infusion of money.

The question is, is that so? I do not know. I do not have the expertise to understand if that is so. Second, if it is so, then I think we ought to know that. And we ought to know whether or not we should put more money into it now to move that time line up.

You know, we are putting money into a lot of other research projects around the country, like supercomputers and things like that. And I am wondering, you know, which, again, in trying to make our choices here, which is the most important choice to make?

Dr. **Raub**. A joint 5-year plan between the NIH and the Department of Energy is in the final stages of development. That plan addresses the sets of tradeoffs such as how much emphasis on mapping of the genome compared to sequencing; how much emphasis on technique development both for the laboratory and for the data handling; how much emphasis on the genome of other organisms other than the human, which are smaller, less complex and whose sequencing can be invaluable in guiding the larger effort toward the human genome. The 5-year plan also focuses on the cost reductions that I mentioned. We are confident in the long run, the broader technology base will be a much better investment than a more heavily front-ended investment made now.

Senator **Harkin**. I see I will have Dr. Watson back up here this afternoon, and I want to get into this some more and why it is going take so long.

I understand the idea of bringing the price down. I have a friend of mine who never buys any video equipment, because he always wants to make sure he gets the best and it just keeps changing all the time. See, the prices keep dropping all the time.

I am just wondering if we are not in that kind of a situation where, by putting some money up front and really moving ahead very aggressively on this project, we will not make more discoveries, especially focusing on those genes that we really want to look at first, like cystic fibrosis.

Dr. **Raub**. I think I also should stress that independent of and parallel with the genome project is the development of human gene sequences associated with diseases of particular interest such as cystic fibrosis, muscular dystrophy and Huntington's disease. This work is funded through our various Institutes in the normal course of research. A broad base of human gene sequencing is developing as a result of the pursuit of these particular diseases and their protein products.

Senator HARKIN. Are these people talking to one another?

Dr. RAUB. Yes; one of the tasks of the genome project, and especially the database parts of it, is to ensure that information arising throughout the scientific community is brought together and packaged in a useful form for everyone.

NIH DIRECTORSHIP

Senator HARKIN. Let me shift gears very suddenly and dramatically on this. I would like to talk a little bit about the directorship.

Since Dr. Wyngaarden left last August a search process has been underway. I understand a number of names were recommended to the Secretary. At least two of those names were recommended to the White House, both of whom either turned down the offer or were turned down—I am not exactly certain how that happened.

I have been informed that some years ago there was a process whereby a panel under the Secretary of Health and Human Services would recommend a name to the Secretary, and then that would be forwarded to the White House. And basically it was done outside of the political realm. And that this was changed, some time in the early 1970's.

I have someone looking into that right now. This just came to my attention a couple of weeks ago and I am trying to get the facts out on that.

Could you enlighten me any on that and what the process used to be and how we can get this out of the political realm and get it back to the scientific community like it used to be?

Dr. RAUB. I think there are two aspects to your question, Senator. In regard to the selection for the position itself, it was in the 1970's that the position of director, NIH became identified as a Presidential appointment subject to confirmation.

Senator HARKIN. Prior to that?

Dr. RAUB. Before that time, I believe the position was an appointment by the appropriate higher levels of the former Department of Health, Education, and Welfare.

Senator HARKIN. It was done by the Secretary?

Dr. RAUB. That is my recollection, sir.

Senator HARKIN. I would like to know more about that. If you could have someone get me more information.

Let us look at some of the directors back in the 1950's and 1960's, how were they appointed, that kind of thing.

[The information follows:]

NIH DIRECTORSHIP

Prior to the enactment of Public Law 92-218 in December 1971, Directors of the NIH were appointed by the Secretary, DHEW (now DHHS). Public Law 92-218, the National Cancer Act, required that the appointment of the NIH Director be made by the President. The requirement was changed further in July 1974, when Public Law 93-352 required that the appointment be subject to Senate confirmation.

The primary option that has been discussed to remove the selection of the Director, NIH, from the political arena is to have the Director serve on a term appointment. Because the Director currently serves at the discretion of the President, no tenure is offered. Some commentators have suggested that recruitment for the position is hampered by a perception that the selection or removal of the Director may be subject to changes in the Administration or in the Department. Additionally, prospective candidates may believe that their decisions and authorities as Director would be limited or influenced by considerations outside those normally associated with biomedical research.

The Director of the National Science Foundation (NSF) and the Surgeon General of the U.S. Public Health Service also serve in high-level science policy positions. Both are Presidential appointees subject to Senate confirmation. However, the Director, NSF, is appointed for a term of six years, and the Surgeon General is appointed for a term of four years (both are renewable). These term appointments may help the positions be perceived as having greater ability to perform the responsibilities of the offices on the basis of the science, rather than on other considerations.

SEARCH COMMITTEE PROCEDURE

Dr. **Raub**. On the other part of the question, I do not know that there was an absolutely uniform process from one time to another. A conventional procedure used even now in the current approach is a search committee. This committee of senior officials, with or without outside consultation, not only consider the names of individuals who come forward or whose names are put forward, but also attempt to identify and interest appropriately qualified individuals in the position.

In the current instance, there is a search committee under the leadership of the Assistant Secretary for Health that is identifying candidates for consideration by the President through the Secretary of HHS.

Senator **Harkin**. Is that under Dr. Mason?

Dr. **Raub**. Yes; Dr. Mason is the chairman.

Senator **Harkin**. Is there a panel? Has there been a panel set up?

Dr. **Raub**. Yes; there is. Since last summer there has been a search committee that has identified names for consideration by Secretary Sullivan. These names were forwarded by the Secretary for consideration by the President and his staff.

Senator **Harkin**. And who set up that panel, that blue ribbon panel?

Dr. **Raub**. The panel was set up at the initiative of Dr. Mason with the concurrence of the Secretary and, I believe, with the expectation of the White House.

Senator **Harkin**. Have there been any recommendations from this panel for restructuring the director's position?

Dr. **Raub**. To the best of my knowledge there have not been formal recommendations from that panel regarding the structure of the position. I believe it has confined itself largely to identifying possible candidates for the higher-level officials to consider.

The Secretary did, however, appoint a separate committee, which is now chartered and has met several times, for the purpose of examining the position itself. The committee is looking at ways that the position might be made more attractive to candidates and how it might function more efficiently and effectively within the Department of Health and Human Services.

Senator **Harkin**. So that panel was set up just to basically advise the Secretary on how to make the job more attractive?

Dr. **Raub**. Yes; more attractive.

Senator **Harkin**. But it is not set up to make recommendations on directors?

Dr. Raub. That is correct.

Senator Harkin. It is a different panel that has been set up to make recommendations on the director.

Dr. Raub. That is right.

Senator Harkin. Are you on that panel? Are you on both panels?

Dr. Raub. Technically, I am not on either panel. I have no relationship to the search committee. I do serve as a staff resource for the secretarially chartered committee that is looking at the empowerment of the position. My colleague, Dr. Fauci, also serves in that same capacity.

Senator Harkin. So you are not on the panel that makes recommendations?

Dr. Fauci. No; I am not on either panel. As Dr. Raub stated, I am an adviser to the panel for making the position more attractive.

Senator Harkin. Have you made recommendations yet on how to make the job more attractive?

Dr. Raub. That committee has not published an official report yet. It has had several meetings, some in public session. There are a number of ideas that have been put on the table and discussed and debated at length. I expect that by the latter part of March or early April, there will be a report from that committee to the Secretary.

I might also mention that NIH does have one of its staff participating on the search committee. That is our Deputy Director for intramural research, Dr. Rall.

Senator Harkin. I would like to see how this was done before and what kind of panel needs to be set up.

I have just heard too many stories that there seems to be some test that proposed directors have to go through in terms of ideology, whether or not they are for fetal tissue research at NIH or associated agencies and things like that. I find it highly disturbing that a person well qualified for that position has to go through such an ideological test.

I have heard too much about this to let it go unnoticed. We have got to get this out of the political realm and back in the scientific realm.

Well, enough on that. Dr. Raub, one thing that has been hanging around for a long time. You and I have talked about this—the so-called Silver Spring monkeys.

I understand you convened a meeting of all the interested parties to resolve the controversy in December after we spoke about this. One suggestion was made to select a mutually agreed upon panel of veterinarians to examine the monkeys and make recommendations as to their care and placement, which all parties would agree to live with in advance.

Where do we stand on this issue? Are we ever going to get this thing settled?

SILVER SPRING MONKEYS

Dr. Raub. Your information is basically correct, Senator. In the early part of December, I convened a meeting of all of the parties to the current litigation to determine what, if any, common ground could be identified and to propose that we explore that type of process.

Since that time, we have had a number of exchanges of letters and we have tried to come to agreement on an expert panel that all sides could respect. NIH has also developed and shared with the other side a set of questions that might be the framework that those experts would address.

Progress has been slow. The gulf that divides us is significant. We are dealing with organizations whose avowed commitment is to abolish animal experimentation. There is little in the way of middle ground that we have been able to identify. We continue those discussions, and we would like nothing better than to find an acceptable resolution to this dispute. At the same time, however, we are committed to holding to the very things for which the NIH exists. We would not favor a settlement that caused us to deny either the unique scientific importance of these animals or, in particular, the prospect for doing something long term about improving human rehabilitation medicine.

Senator **Harkin**. I just want to know if you are supportive of setting up a panel of mutually agreed upon veterinarians? The panel would examine the monkeys and make a recommendation that both parties would agree to in advance?

Dr. **Raub**. Yes; I was the one who articulated that particular scenario.

Senator **Harkin**. Make that clear for the record.

Dr. **Raub**. My rationale was that the litigation can be long running, and that litigation is rarely in everyone's interest to pursue. If we can find an out-of-court settlement that is acceptable to all parties and does not cause us to deny the NIH mission itself, then we will continue to strive for it.

Senator **Harkin**. Has the panel of veterinarians been selected yet?

Dr. **Raub**. Not yet. We have not been able to come to agreement on a full panel. We have been exchanging names and curricula vitae and comments on the members.

Senator **Harkin**. I read a story recently that was in the Post or the New York Times. And I do not know where the truth of this lies.

There is a famous picture that all of these so-called animal rights enthusiasts have used of a monkey that is in a contorted position in some kind of a machine. Do you know what picture I am talking about?

Dr. **Raub**. Yes, sir.

Senator **Harkin**. This article that I read said that some people had entered the premises of where these experiments were taking place and put this monkey in that position for the purpose of taking a photograph of it.

Do you know what story I am talking about?

Dr. **Raub**. Yes; I do.

Senator **Harkin**. Is this factual?

Dr. **Raub**. There are conflicting accounts of the story, and I do not have all the information to verify one account over another. The particularly contorted position of the animal is quite out of character with anything that one expects a group of qualified scientists to do. There is a substantial indication that it was either staged or taken in an interim period that does not provide an accurate representation of the care of those animals.

Senator **Harkin**. I would like to get this issue behind us. I want you and the public to know where I stand on this issue. I believe that animals provide a very valuable resource—an invaluable resource to scientific inquiry.

And certainly I can say without exception that every scientist I have met who is involved in using animals anywhere from mice to the higher primates for scientific research has been solicitous of the animals. He or she has taken due care and concern for those animals, but nonetheless has followed the scientific inquiry for the benefit of mankind.

I believe that is what we ought to be doing. I support the use of animals in research projects, understanding that it should be done in the most decent, careful, considerate manner.

You will have my support in the further use of animals in science to the extent that I can give you that support.

Last year the committee provided $15 million for extramural construction and suggested a number of projects which should be considered for funding. I understand the decision has been made to allocate up to $10 million of that $15 million for the mouse breeding facility which was damaged in the fire last year.

Can you tell us anything about the status of the decision that is affecting the allocation of the remaining $5 million?

EXTRAMURAL CONSTRUCTION

Dr. **Raub**. Yes; I can. If I may, I would like to take a step backward to the larger context.

Our strategy is based on our analysis of all of the applicable statutes, including the special authorization bill for a mouse breeding facility, the special language in the appropriations bill as well as our authorities in three Institutes for construction programs.

The $15 million was generated, as the appropriations bill allowed, setting aside funds within each of the NIH by Institutes appropriations. Before this was done, the $15 million was reduced to $14.8 as a result of sequestration.

We then developed a strategy using two requests for applications. One focused on a single mouse breeding facility large enough to meet national and international resource need. The second was for all other construction projects falling within our collective authorities. Special emphasis was given to ensure that all of the institutions identified in the Senate appropriations bill report, to the extent that the law allowed, could compete for funding.

We then determinated that, because of the really unique significance of the mouse breeding facility problem that, $10 million would be available for that project.

The awarding of these funds will be subject to competition and peer review. Should the best proposal not be able to justify the full $10 million, we would make the award at the appropriate technically determined amount and make any residual funds available for the other competition. Our intent, however, is to be unequivocal in terms of the unique significance of the mouse breeding facility and to assure that, consistent with the authorization bill, an adequate sum is available to support it..

For the remaining areas, our focus will be within the collection of other authorities that NIH has, namely, cancer; heart, lung and blood; and eye. I interpret the committee's intent that we take a reasonably broad interpretation of those mandates and we will make every effort to ensure that all possible candidates for funding will compete. In addition, because nationally competed and reviewed high-quality cancer construction programs were available, we allocated $2 million to Dr. Broder with the expectation that he will negotiate some appropriate awards with the top three facilities on that list. Should he not need the entire $2 million, the residual amount would also be available for subsequent competition.

Senator HARKIN. So, of the five remaining, you say you have allocated two that are already approved.

Dr. RAUB. That is correct.

MORATORIUM ON HUMAN FETAL TISSUE RESEARCH

Senator HARKIN. Returning to an issue I mentioned in regard to the search for a new director, on March 22, 1988 the Assistant Secretary for Health initiated a moratorium on Federal funding for transplantation research using human fetal tissue derived from induced abortions. That moratorium has been confirmed by Secretary Sullivan.

Could you address the research opportunities we are missing because of this moratorium?

Dr. RAUB. Strictly speaking, at the time it was issued, there were two research projects affected by that moratorium. One was a project not yet begun in our intramural program that would have involved the transplantation of human fetal cells into the brain of a patient with Parkinson's disease. The other was an extramural project at the University of Wisconsin, in which human fetal cells were transplanted under the kidney capsule in the hopes of countering some of the effects of diabetes. Technically, as an ongoing grant project, this extramural project was not covered by the moratorium. However, the scientists involved voluntarily stopped the work until the human fetal tissue transplantation research panel presented its findings.

Senator HARKIN. The scientists at the University of Wisconsin?

Dr. RAUB. That is correct.

Senator HARKIN. They voluntarily ceased it? Why, if it was not affected by the moratorium?

Dr. RAUB. I believe it was in his recognition of the intensity of the national debate, the deep differences of opinions, and electing to wait for the outcome of the panel's deliberations before proceeding with this line of research.

Senator HARKIN. I was unaware of that one. I was aware of the one dealing with Parkinson's disease. And you say that had not yet begun, but all of the groundwork had been laid for it?

Dr. RAUB. That is correct.

Senator HARKIN. And there was every indication that that this would prove to be a good ground for research into how to arrest Parkinson's disease?

Dr. **Raub**. Since it is research, by definition no one could say with certainty in advance whether the project would work. There was adequate justification from animal experimentation and from clinical trials attempted elsewhere in the world to proceed.

Senator **Harkin**. You mentioned these two specific projects. But what are some of the broader areas in science that are affected by this moratorium?

Dr. **Raub**. Had there been other transplantation research projects with human subjects, then they too would have been arrested. I do not have specific figures on any others. The ban does not apply to those few instances where human fetal tissue is used routinely in established treatment.

There are some rare disorders where that therapy is used, and the ban does not affect that. The moratorium strictly applies to research. Moreover, the ban does not affect nontransplantation research uses. NIH has about $7.3 million worth of ongoing research where human fetal tissue is used in laboratory studies. For example, research is being supported to look at the so-called growth factors that are active in early embryonic life. These factors not only play a role in growth and development, as their names implies, but increasingly are being linked with cancer and in the long term, even with problems in the aging process. That research continues.

Senator **Harkin**. So you are saying that the moratorium does not apply—enlighten me again, I want to understand this—does not apply to nontransplantation research projects. Is that the correct——

Dr. **Raub**. That is correct. Let me state it the other way, Senator. The moratorium applies to human fetal tissue that is derived from induced abortions and used in research involving transplantation into human subjects.

Senator **Harkin**. So what would be the other use if it is not used for transplantation?

Dr. **Raub**. Fetal tissue not used for transplantation might be used in a variety of laboratory studies. For example, it is used to look at the biochemistry of these cells, how they grow and divide, and how they develop, in order to get a better understanding of the earlier stages of life. That basic science continues.

Senator **Harkin**. So when you talk about a moratorium on fetal tissue research that is not entirely correct.

Dr. **Raub**. That is correct.

Senator **Harkin**. There is just a moratorium on transplantation research.

Dr. **Raub**. Yes; the moratorium is for transplantation research into human beings.

Senator **Harkin**. Well, I will have to look at this more. I understood the problem with using fetal tissue but did not understand that there was a problem with the transplantation research. So if it is used for something else, other kinds of research, then it seems to me the original arguments for not using it do not hold.

Dr. **Raub**. There have been many points of view offered. As I understand it, the ban posed by the former Assistant Secretary for Health and continued in the current administration was drawn as specifically as it was due to concern that greatly expanded use in the human clinical transplant arena could create a new demand for abortion. It was that concern over the change in the national scene with respect to abortion that caused the moratorium to be placed.

Senator HARKIN. If it was not an induced abortion, you could still use it for transplantation research?

Dr. RAUB. That is correct.

APPROVAL RATES

Senator HARKIN. Let us talk about the approval rates. I mentioned in my opening statement that NIH currently approves 95 percent of the grant applications. In 1982, it was only 85 percent. Each year since 1982 the percentage of grants approved has increased.

Why is this happening? And is a 95-percent approval rate too high?

Dr. RAUB. We have been watching those trends very carefully and attempting to analyze them and understand the factors that are at work. We think that the principal factor is the consequence of increased competition. That is, it is the hardier souls that are staying in the competition. Many of our grant applications are now renewal requests or from individuals who have been unsuccessful previously, and have attempted to take the benefits of the review process to further their thinking and try again. We also believe there has been an upward shift in the mean quality of applications as the competition becomes more severe and our investments in both research and training pay off.

We cannot discount the possibility that some of our review groups may be grading a little more easily than they might have in the past. They may recognize that someone approved and unfunded may be able to obtain private funding and that someone disapproved might have a non-negotiable barrier in terms of seeking private funds. I cannot discount that force being at play. However, my professional judgment and that of my colleagues is that it is far outweighed by the factors of higher mean quality and a more intense competition.

Senator HARKIN. A 95-percent approval rate seems to be very high. Would it be desirable for NIH to exercise greater selectivity at the front end of the process, in light of the fact that we clearly cannot fund 95 percent of the grant applications?

We obviously cannot fund that, so if you are not making the decision, we have to make the decision, and I do not know that that is something that we ought to be doing. We should not be making those decisions here.

Dr. RAUB. We have looked at a number of ways that we might facilitate the process. In certain instances where we have been soliciting applications on a particular topic, it has been helpful to have a preliminary step that we call a triage. However, in general, our conclusions have been that, applied across the board, it would not be very effective or very efficient. Our best course is the fundamental peer review system, as we have always operated it, and to assure that the process flows as efficiently as possible.

Senator HARKIN. Tell me about the length of time. In 1981, the average length of grants was 3.3 years, and now it is 4.2 years.

This, of course, results in more of the available funding being devoted to grant continuations and a smaller proportion being available for new grants.

Should we continue the practice of funding grants for as long as 5 years, or should we fund them for shorter periods of time?

Dr. **Raub**. We have also been tracking that very closely. In this instance, the forces are more readily identified. As you have said, it was NIH's own initiative, going back several years, to promote longer periods of awards.

If I may, I will take a few minutes to reconstruct the environment that caused us to do that. When we first began to be concerned about awards being of too short a tenure, we were finding situations where leading scientists were spending far too much time in the business of reapplying, writing progress reports and new applications, rather than in the business of doing the science itself. The most extreme stories were those of the young people who, upon receiving their first grant for 3 years, spent 1 year to 1½ years getting the laboratory established, only to have to turn around within 6 months and write a progress report and reapply, in the hopes of getting continued funding. They found themselves judged nominally on 3 years, but, in fact, 6 or 9 months of work were all they really had to report on. Within that context, Dr. Wyngaarden, with strong support from me and others, made the policy decision to encourage the individual institutes and the national advisory councils to consider longer-term awards.

In addition, some special mechanisms to encourage longer-term awards, both for first-time applicants and for midcareer scientists, were put into place. However, the decisionmaking was decentralized. That is, rather than being done on an across-the-board NIH basis, it was left to the judgment of each Institute and its national advisory council.

As we analyze it, over the last several years, we see considerable variance across the Institutes. At the one extreme, there are those Institutes and their councils who are concerned, as you said, that they may have too much money in the so-called noncompeting continuation lines, and not as much resources as they would like available for competing grants. Others, by their own characterization, were very conservative all along and either are content to hold at about their level of commitment to the long-term grants, or might even increase it a bit. Still others find themselves about right. After looking back for several years, they believe the new balance point they have reached is, all things considered, the best pattern of investment for them.

Over the last several months, our view has been not to impose any NIH-wide change any more than we would have imposed an NIH-wide mandate to start. Rather, we have encouraged each one of the Institutes and their councils to look hard at the balance and to be responsible to themselves and to their scientific and public constituencies as to the best allocation between continuing awards and new ones.

Senator **Harkin**. What I hear you saying is that if in fact some of the Institutes are basically keeping the mix the same as it was before, let us say, at the 3.3-year level average, if the total average now has gone up to 4.2 years, that means some Institutes have gone beyond that, and have pulled the average up.

Dr. RAUB. I believe that all of them have in fact increased the average length. It is just that some have increased it only a small amount, and others have increased it much more.

Senator HARKIN. What Institutes would have increased it the most?

Dr. RAUB. I believe the National Cancer Institute, the National Institute of Neurological Disorders and Stroke, and the National Institute of General Medical Sciences are among those that have had major increases.

Senator HARKIN. Cancer and Medical Sciences and Neurology?

Dr. RAUB. Yes.

SALARY CAP ON NIH FUNDED RESEARCHERS

Senator HARKIN. Last year, in an effort to help control the escalating costs of grants, the Congress accepted the administration's recommendation, and included a cap of $120,000 on the salary that any NIH-funded researcher could earn from an NIH grant.

To your knowledge, Dr. Raub, has this caused any operational difficulties?

Dr. RAUB. I am not aware of any operational difficulties. We were able to develop a means to administer it quickly and apply it in the early part of the fiscal year. To the best of my knowledge, all of the awardee institutions have assimilated it, and it is working smoothly.

NIH POSTDOCTORAL FELLOWS

Senator HARKIN. Let me ask one followup question to that, lower on down the spectrum. What is the average that you pay now for a postdoctoral research person to come to NIH to do postdoctoral research? How much a year do you pay?

Dr. RAUB. In the range of $30,000.

Senator HARKIN. Lower for some, higher for others?

Dr. RAUB. Yes.

Senator HARKIN. I heard the average was more like about $26,000 or $27,000, as an average.

Dr. RAUB. In our extramural fellowship program supported through National Research Service awards, the starting levels are around $17,000, going up to about $31,500.

Senator HARKIN. That is not at NIH?

Dr. RAUB. No; those are fellows receiving extramural grant funds.

Senator HARKIN. On the outside.

Dr. RAUB. A small portion of those individuals could be taking their training at NIH.

Senator HARKIN. Describe one of those postdoctoral research fellows. How old would this person be? How much schooling would they have under their belt?

Dr. RAUB. Typically, the individuals would be in their late-twenties, having completed 4 years of baccalaureate college and 4 to 5 years of graduate work leading to the Ph.D. They are intensely interested in a research career and look to the postdoctoral mechanism both to refine their talents and skills in particular areas and to gain the exposure to research-intensive laboratories and a broader group of colleagues.

Senator **Harkin**. And some of them, in the case of perhaps medical doctors, would be in their early thirties, I would assume?

Dr. **Raub**. That is correct.

Senator **Harkin**. Medical doctors had gone to school a little bit longer, a Ph.D. may be a little bit shorter period of time?

Dr. **Raub**. That is correct.

Senator **Harkin**. Maybe married, probably have got one or two kids, maybe?

Dr. **Raub**. Yes.

Senator **Harkin**. They have debts piled up from college. How can they live in this area on $27,000 a year?

Dr. **Raub**. Not easily.

Senator **Harkin**. I do not know how they do it. I think we have got to take a look at that. Some postdoctoral fellows on the outside get as low $19,000 or $20,000 a year and are hard-pressed to live, especially with school debts.

What I do not understand is why a young person who may be at the top of their class, and really interested in a research project, wants to devote at least some time of their life after they have gotten their doctoral degrees, either M.D. or Ph.D., to examining some bit of research? How can they afford to do that and pay back their college loans and even live?

Is there any possibility of getting those salaries up? I think it is a scandal, the small amount of money that is being paid to these researchers.

I just intuitively feel that we are losing some of the best, some of the brightest minds out there, who want to do this kind of work. However, for that amount of money, they cannot pack up and move themselves, or devote 3, 4, or 5 years of their lives to following some research projects that they are intensely interested in.

Am I missing the mark on that?

Dr. **Raub**. No, sir; I think that is a continuing concern. We always have to be mindful of the opportunities those individuals have on the outside, not only for research in universities, but also in industry. Because of the high variability in cost of living around the country, many of the recipients of our extramurally funded research training grants use private funds to supplement stipends and other assistance for living costs as a way of making a national number fit the particular requirements of their localities.

[The information follows:]

NIH Postdoctoral Fellowships

The National Institutes of Health has two major categories of postdoctoral fellowship programs. These include training fellowships and service fellowships.

Training fellowships are established for the principal benefit of the participants. These fellowships are granted to newly qualified physicians and Ph.D. level investigators with less than three years of relevant research experience, to enhance their research capabilities in the early professional stage of their careers. Participants are not NIH employees, but rather receive a stipend award to support a period of full-time study, training, and practical research experience in NIH intramural laboratories.

Service fellowships are established for the mutual benefit of the NIH as well as the participants. These fellowships are for physicians and Ph.D. level scientists with

7 or less years of relevant research experience at the time they enter the program. Service fellows are non-permanent employees of the NIH, participating in developmental research assignments that foster their maturation as fully qualified and creative independent investigators. Those who prove most able may be offered permanent employment by the NIH at the conclusion of their fellowships.

The NIH uses a market based compensation system to establish stipend levels for its postdoctoral programs. Pay levels are set and adjusted based on data and issues relating to internal equity between fellowship programs. Each year, NIH conducts a stipend level survey of prominent and prestigious medical schools and universities across the country, with particular emphasis on the northeastern corridor, to ascertain current stipend levels for postdoctoral graduates with varying degrees of experience. Survey questions relate to basic stipend levels, differentials between Ph.D.'s and M.D.'s, housing allowances, tuition benefits, and life and health insurance. The results are considered by the NIH Board of Scientific Directors. The Board's recommendations are presented to the Director, NIH, who determines the final postdoctoral stipend rates.

Stipend adjustments have historically been effected at the same time as the comparability increases granted for general schedule employees. Rates are set to be competitive with prevailing market rates. New stipend levels apply to both current staff and new hires. However, since stipend levels are administratively determined, rates may be increased at any time market conditions warrant adjustments.

The following represents the current stipend ranges for NIH programs. Individual stipends are set based on the amount and quality of the post-graduate experience of each scientist accepted for an NIH fellowship. Annual stipend increases average $1,000 to $2,000 per fellow.

	Range of stipends
U.S. fellowship programs:	
Service fellowships Ph.D	$24,000–$46,000
Service fellowships M.D	28,000–54,727
Training fellowships	25,000–28,000
Visiting foreign scientist programs:	
Visiting fellowships	25,000–47,000
Training fellowships	25,000–28,000

REMARKS OF SENATOR SPECTER

Senator **Harkin**. Dr. Raub, thank you very much. I did not intend to take this much time, but I wanted the opportunity to cover a broad range of concerns that I have on these issues.

I recognize my friend from Pennsylvania, Senator Arlen Specter.

Senator **Specter**. Thank you, Mr. Chairman.

I regret my late arrival. The Defense Subcommittee appropriations is hearing from the Under Secretary, and I had to be there, and the Judiciary Committee is meeting, which I will have to excuse myself soon for. I know you understand that we have many hearings scheduled each day, and often at the same hour.

I do appreciate the tremendous importance of these hearings and the extraordinary work which the National Institutes of Health is doing and the very many matters that you are undertaking.

I am glad to see that there is some increase, not enough, with all of your responsibilities, and I will study the hearings and give careful thought to the matters which you have before the subcommittee.

Just a couple of questions, because I know there are many witnesses to follow.

I note that there has been approval of a project in Pittsburgh, the Pittsburgh Cancer Institute, which was peer reviewed in 1989, and approved on a $1 million project for $864,000. And that the fund that might have been appropriate was a $15 million NIH-wide extramural construction allocation.

Some $10 million has been allocated for a special facility for mouse breeding, which last year was destroyed by fire. I will not go into why so much of the $15 million was allocated there.

After a sequestration for $200,000, $4.8 million was left and the NIH Director, according to the information provided to me, has decided to use $2 million to fund previous approved projects, and, putting $2.8 million out for new competition.

Aside from my real question, which is, why has Pittsburgh not received its funding? Let me start with the question as to why you are going out for new competition for $2.8 million when you have other projects which have been approved and are waiting in the wings, and are presumptively or obviously well-qualified, important projects?

EXTRAMURAL CONSTRUCTION

Dr. **Raub**. In designing the solicitation related to the $15 million, we took into account all of the laws and the legislative history relating to that money. As you mentioned, the $10 million sum was made available for the national competition for a single mouse-breeding facility because of the unitary significance of that to the national effort; $5 million remained, minus the sequestration amount.

Senator **Specter**. Is there any special emphasis for Maine on that allocation? I wonder, with $10 million out of $15 million, and $25 million comes up on a special authorization from Congress. I mean I know Iowa is not involved in this bidding, but Pennsylvania is in the wings.

But go on to your next point about the $4.8 million.

Dr. **Raub**. With the $4.8 million remaining, one of the first things we did was determine what nationally competed, peer reviewed and approved construction projects already were in hand. We then looked very carefully at the legislative language and history. The legislative language is quite clear that more than cancer research facilities are to be involved in the competition for the funds. Therefore, we did not think it was consistent with the various directives to make the money available exclusively for cancer centers.

Senator **Specter**. Was the $2 million allocated for cancer?

Dr. **Raub**. Yes; the only applications approved and unfunded in-house involved cancer facilities. In looking at the list of those available, it was our determination that the several at the very top of that list were not only pertinent to the legislative guidance on that money, but, in fact, were near flawless in their technical quality. These were projects that we should move on right away. On that basis, I made available $2 million for the Director of the National Cancer Institute to make the appropriate funding arrangements for those top three grants.

Senator **Specter**. Well, why do you think there is not legislative intent to use all $4.8 million for cancer? That is not much money, and cancer is a tremendous problem—I do not have to describe the scope of the problem in this room. And there has been a very specific congressional statement about directing resources, really, far beyond the funds in question, to cancer.

Dr. **Raub**. Well, the cancer facilities undoubtedly are and must be included in the competition for the funds. As we read the record, however, the original Senate list went beyond cancer facilities, to include explicitly some other types of research facilities. In addition, the language associated with the conference report makes very clear the expectation of national competition. It is our attempt to synthesize all of that guidance.

Those applications that remain approved and unfunded will be considered further, either as they stand or with whatever supplemental information they would want to submit, in terms of the competition for the remaining $2.8 million.

Senator **Specter**. But, if your conclusion is that you want to go beyond cancer, and you are getting new bids in, it seems to me that if you are going to make an award, hypothetically, to Pittsburgh, of $800,000 plus, you would have already made it.

I just have a question as to going out and looking for new projects and new bidding at a time when you have important projects which are awaiting funding, and that money is in hand, and it could be used. And it is going to take considerable time to make new awards. You have to get new proposals. And there has to be competitive review.

And Senator Harkin and I may make available so much money to you that you can fund those anyway. [Laughter.]

I think Senator Harkin just nodded in agreement. [Laughter.]

Senator **Harkin**. You offer it, I will support it.

Senator **Specter**. Well, I would like to see you take a closer look at Pittsburgh. But I would also like to see a little more thought to utilizing that much money. It is not a tremendous sum of money, $2.8 million, solicit new projects.

I understand the considerations you have to balance, and I appreciate the fact that it is your judgment call in the final analysis. But, as I read this record, on the $15 million, then on the $4.8 million, and on the $25 million, et cetera, I am just a little disappointed in what has happened, really. And it is an admittedly parochial interest.

Let me ask a question on a separate topic.

I have seen a fair amount of press on the subject of the use of marijuana for medical purposes, as a pain killer for people who are being operated on for cancer. And I have seen the conclusion that it is not available because of restrictions in our criminal laws on the use of marijuana.

I would be interested to know, if you have the information at your disposal, what are the pros and cons of using marijuana as a pain killer in operations for cancer, and what legal limitations apply at the present time, so that we might give some consideration to congressional action to make a change in that, if in fact it is warranted?

MARIJUANA AS A PAIN KILLER

Dr. **Raub**. My knowledge on that is somewhat dated, sir. If I may, I would like to have our Directors of the National Cancer Institute and the National Eye Institute provide some information for the record.

Marijuana has been advocated not only in pain control in cancer, but in reduction of the interocular pressure in the eye, associated with glaucoma. The latest information I have available, which is not recent, was that the alternative legal means available to the same clinical end were viewed by many people as sufficient. Therefore, many did not argue for any special consideration of marijuana. If I may, however, I would like to have the experts provide you an answer.

Senator SPECTER. So you think that it may be available now on prescription by a physician to use marijuana as a pain killer in those circumstances?

Dr. RAUB. I am just not up to date on the facts, and I would prefer that the experts provide an answer.

Senator SPECTER. Well, fine, I can well appreciate a specific question like that requiring some specific review. And I would appreciate it if you would submit that for the record.

Dr. RAUB. All right. Thank you, sir.

[The information follows:]

USE OF MARIJUANA

Marijuana is still an investigational drug and therefore it is not commercially available. The National Institute of Drug Abuse holds the Investigational New Drug Application (IND) for marijuana.

Delta-9-tetrahydrocannabinol (THC), which was isolated in 1964, is the major psychoactive constituent of marijuana. THC is considered a separate drug from marijuana by the FDA. There have been several proposed uses for THC, the control of nausea/vomiting, pain, and treatment of glaucoma.

The National Cancer Institute (NCI) filed an Investigational New Drug Application (IND) for THC with the Food and Drug Administration (FDA) in September, 1978. In October 1980, the FDA approved the distribution of THC under the Group C designation to physicians for use in patients who were resistant to other forms of antiemetic therapy.

In May 1986, the FDA approved the New Drug Application for THC, making it commercially available. Roxane Laboratories of Columbus, Ohio markets THC under the name Marinol for the control of nausea and vomiting associated with cytotoxic therapy. The FDA has not approved the use of THC for treatment of pain. However, since Marinol is commercially available, physicians in the United States may prescribe it for any indication for which they feel it is medically warranted.

While there is evidence that THC is more effective than placebo for the nausea and vomiting associated with cytotoxic therapy, currently the analgesic properties of THC are not evident. THC is euphorigenic and this property might provide a sense of well being for patients in pain.

In regard to the treatment of glaucoma, there is evidence that marijuana (or certain of its components), taken orally or smoked can lower intraocular pressure. However, there are no conclusive studies to date to indicate that marijuana—or any of its components—can safely and effectively lower intraocular pressure enough to prevent optic nerve damage from glaucoma. Furthermore the dose of marijuana necessary to produce a clinically relevant effect in the short term appears to produce an unacceptable level of undesirable side effects such as systemic hypertension, dry eye, and euphoria in the majority of patients studied. In addition, there are no published studies of ocular and systemic effects of long-term use of marijuana by glaucoma patients. This lack of long-term studies is significant because glaucoma is a chronic disease that requires ongoing therapy.

There are several drugs approved by the Food and Drug Administration (FDA) for use in treating glaucoma, and those are the drugs of choice by most, if not all, ophthalmologists for treating this disease.

RESEARCH TRAINING PROGRAM

Senator **Specter**. Thank you very much, Dr. Raub.

And thank you all for coming and providing the information.

Thank you, Mr. Chairman.

Senator **Harkin**. Thank you, Senator Specter.

Senator Bumpers, do you have anything for the record?

Senator **Bumpers**. Thank you, Mr. Chairman. I have two or three items I would like to discuss with the good doctor.

I want to ask first of all, have you asked for any money to increase postdoctoral training programs for scientists at NIH?

Dr. **Raub**. There is an increase requested for extramural research training, an expansion of approximately 225 trainees in total.

Senator **Bumpers**. How does that compare with last year?

Dr. **Raub**. The total is up by 225 from last year's number.

Senator **Bumpers**. Up 225 from last year's number?

Dr. **Raub**. Yes; to a total of just over 12,000.

SENIOR SCIENTISTS AT NIH

Senator **Bumpers**. Have you asked for increases in salary for senior scientists at NIH?

Dr. **Raub**. There is not an explicit request in the budget for that, since we are guided by the normal salary policies of the Federal Government. However, to the extent that the recent pay raise applies to us, those estimates have been built into our budget estimates. There is no separate pending request for higher salaries in this budget.

Senator **Bumpers**. Well, I think this year the Senate will probably join the House at the $120,000 level. And I guess at that point we will be very generous and authorize you to do the same. That would solve a lot of your problems, would it not?

Dr. **Raub**. As we determine it, much of the gap for our Ph.D. scientists, between what we now pay them and what their counterparts in academic institutions make, would be eliminated if the estimated pay raise for January 1991 comes into place.

The increase also would be welcome for our physician scientists, but the gap is much stronger there. Currently, the difference is a factor of two, between what we are able to pay a senior physician scientist and what the comparable position in a leading academic institution would be.

Senator **Bumpers**. Well, just for the record, 61 percent of the physicians at NIH said they had received offers ranging from $100,000 to $500,000; 47 percent said they had been offered at least $10,000 more than their current NIH earnings; 83 percent of the senior level NIH physicians received offers averaging $166,000, or approximately twice their current compensation.

And this chart goes on, and Mr. Chairman, for the record, I would just offer these statistics. Here is a list of statistics on the pay and the offers that scientists and physician researchers have received.

I think it is a real crime that we have not been able to deal with the salary issue, if necessary, in a vacuum, and separate from everybody else. I certainly do not feel that a senior researcher at NIH must necessarily be constrained by the political constraints under which I operate.

[The information follows:]

NIH RESEARCHERS

The following is a list of NIH researchers who have left NIH for universities or private biomedical research organizations. All have received substantial salary increases (up to three times their government salaries), and improved benefits.

Dr. Marc Lippman of the National Cancer Institute, one of the country's leading experts in breast cancer, left NIH to accept a position to direct the Lombardi Cancer Research Center at Georgetown University. In addition, five of his senior colleagues are accompanying him. All will be receiving substantial increases in salary. Their departures are seriously threatening the capability of NCI to provide care for cancer and AIDS-patients.

Dr. Michael Zasloff of the National Institute of Child Health and Human Development, has accepted a post at the University of Pennsylvania. Dr. Zasloff has recently discovered magainins, a remarkable family of natural antibiotics produced in frog skin that are the key to a previously unknown set of defenses against diseases and hold the promise of being more versatile than any other class of antibiotics.

Dr. Robert Lazzarini of the National Institute of Neurological Disorders and Stroke is departing to accept a position at Mt. Sinai Medical Center. Dr. Lazzarini has made great strides toward understanding and possibly treating genetic demyelinating diseases, such as multiple sclerosis and Guillain-Barre disease.

Dr. John Sever of the National Institute of Neurological Disorders and Stroke has left the Laboratory of Infectious Diseases to become Chief of Pediatrics at Children's Hospital of Washington, D.C. Dr. Sever is a leading researcher in the virology of pediatric disorders and the role of perinatal infections in the production of fetal damage.

Dr. Vincent DeVita, Director, National Cancer Institute, accepted a position with Sloan-Kettering. Dr. DeVita is an internationally recognized and respected scientist who led the National Cancer Institute with great energy and vision.

Dr. Robert Wittes, Associate Director of the Cancer Therapy Evaluation Program, National Cancer Institute, is also leaving NIH to accept a position with Bristol Meyers. Dr. Wittes was responsible for setting up a national network of cooperative clinical groups who conduct trials for testing and understanding new treatments for cancer on a national basis. His loss will have a major adverse impact on the testing of new cancer treatments.

SENIOR LEVEL SCIENTIFIC RECRUITMENT, RETENTION, AND PAY

NIH physicians in the Senior Executive Service are paid an average of 49 percent less than their counterparts in American Medical Schools.

Other NIH doctoral scientists average 19 percent less in pay than comparable scientists in research intensive universities.

NIH just completed a survey of employment offers made to its scientific staff within the last two years. Of the 371 permanent staff responding: 61 percent of the physicians reported they had received offers ranging from $100,000 to $500,000; 47 percent of the Ph.D. scientists received offers of at least $10,000 more than their current NIH earnings; 83 percent of the senior level NIH physicians received offers averaging $166,000 or approximately twice their current compensation; 66 percent of the other senior level doctoral scientists received offers averaging $105,000 or approximately 50 percent more than their current salary.

In the last 10 years, NIH has: Not been able to recruit a single senior research scientist from outside the Government into the SES; and experienced a net loss of 28 percent of the intramural research scientists in the Senior Executive Service.

A large number of NIH SES members are close to retirement: 59 percent of the NIH intramural SES scientists are eligible to retire now. An additional 18 percent will be eligible within the next five years; and 50 percent of the NIH SES administrators and science-managers will be eligible for retirement within the next five years.

NIH POSTDOCTORAL RESEARCHERS

Senator **BUMPERS**. But let me just shift gears for a minute.

Senator **HARKIN**. If the Senator would yield on that.

Senator **Bumpers**. Yes.

Senator **Harkin**. Before you arrived, I covered a little bit of that with Dr. Raub. But I also asked them to focus on what they are paying postdoctoral researchers. We covered that briefly here.

These are the young people that have been to graduate school, through medical school, in their late twenties or early thirties, at the top of their class. They are bright and want to devote some of their time to research at NIH. Their minds are uncluttered, they are open. They want to investigate, perhaps, new and exciting areas.

And do you know what they are paying them right now, $27,000 to $30,000.

Now I ask you, how can someone live out here on that with their wife, and one or two kids? How do they pay off their college bills on that kind of a salary?

Senator **Bumpers**. And I assume that is the pool from which we expect in the future to draw senior scientists, is it not?

Dr. **Raub**. Yes, sir.

Senator **Harkin**. The scientists' salaries at NIH need to be addressed, not only the senior scientists that need to be addressed, but these new young people coming on board.

Senator **Bumpers**. Well, it has to be a labor of love. I see all your staff back in the audience nodding, yes, that is true. [Laughter.]

AWARD RATES

Dr. Raub, let me ask you about the number of new and competing grants that you can make, because I think this is extremely important, too. In 1988, you awarded approximately the top 35 percent of the grant applications; 35 percent just 2 years ago were funded; in 1989, 29 percent; this year about 24 percent; and in 1991, it is projected only the top 25 percent.

Now this is a very dicey comparative analysis. Because, to suggest that you ought to be funding 100 percent does not make any sense. I am sure you receive some applications which should not be funded.

But I have always understood that NIH feels certain that at least 35 to 40 percent of the applications are meritorious and ought to be funded. Is that a fair statement?

Dr. **Raub**. Yes, sir; whenever we have an opportunity, as part of the budget process, to develop a professional judgment, we normally use the order of a 45-percent award rate as an indicator. This is based on historical experience.

Senator **Bumpers**. Well, you are only asking for a small, something like a 4-percent increase this year in your budget. How does that take care of those applicants? And most of the applications I assume are on a multiple-year basis, and they have inflationary requirements, too. Is this enough to take care of their inflationary needs?

Dr. **Raub**. Within the overall request of 4.7 percent, there are inevitably a number of tradeoffs and priorities that must be set.

One of those is the balance between research project grants and other types of also very important awards, such as research centers and research training. At this level we try to make an allocation that is a balanced and effective configuration across the funding mechanism.

Within the research project grants mechanism, as we were discussing earlier with the chairman, each of our national advisory councils and boards and institutes have struggled with how hard to emphasize long-term awards, such that scientists can have the stability of funding, and what special steps should be taken to ensure that the new and the so-called competing renewals have a reasonable opportunity each time.

The 25- and 24-percent number for next year and this year, respectively, is where the award rate for project grants comes out, when one takes into consideration everything, from the overall dollar request to the many important competing demands upon the budget.

Senator **Bumpers**. What did the professional judgment budget assume in terms of award rate?

Dr. **Raub**. Last spring, in the earliest stages of the budget process, using the 1990 President's budget as the base, we estimated that a 45-percent award rate would translate to about 8,800 competing research project grants.

Senator **Bumpers**. Well, how much did you request in your professional judgment budget?

Dr. **Raub**. It was not a secret message, sir. It is built into the budget process. The very first stages give us the opportunity to develop a professional budget level along with our approaches to other more constrained budget levels. The NIH requested a budget of approximately $11 billion at the professional judgment level for fiscal year 1991.

Senator **Harkin**. Excuse me. Was that the bypass budget request?

Dr. **Raub**. No; this was our submission to the Assistant Secretary for Health, along with our approaches to more constrained budget levels.

Senator **Bumpers**. And you come here asking for less than $8 billion, is that correct?

Dr. **Raub**. Yes, sir; $7.9 billion.

Senator **Bumpers**. Well, I do not want to get preachy, but I just keep saying our priorities are so screwed up in this country I cannot believe it.

I just came from defense appropriations, where I told the Assistant Secretary of Defense the same thing. And if there is going to be a peace dividend, of course Congress is going to have to carve it out. Obviously, the administration has just discovered that the Third World now is a bigger threat than the Soviet Union was. [Laughter.]

And so we are going to have to keep spending $300 billion plus to take care now of the Third World. And you are going to keep getting whatever is left.

I feel very strongly about NIH, and I feel very strongly that we ought to get the awards rate up to 35 to 40 percent minimum, and that you ought to be paying people out there, and not taking advantage of their love of research and the exciting environment in which they work at NIH. And sometimes they are not so wonderful. I have been out there and I have seen all that clutter in the hallways, too.

But it is just a tragedy that we have to do that.

Well, I will reserve my remaining questions for the directors of the Institutes.

Senator **Harkin**. Senator, I thank you for your contribution. I wanted to be at defense appropriations also to ask a question about the over 200-percent increase that they are requesting for the follow-on to the Lance missile. Did you get into that?

Senator **Bumpers**. We did, and I thought that was too absurd to even question about that. [Laughter.]

Senator **Harkin**. This is a follow-on to Lance missile which has to be less than the intermediate range. By agreement with the Soviets, it has to be 310 nautical miles or less. Which means, if launched from West Germany it can hit East Germany or Poland.

Senator **Bumpers**. Or West Germany.

Senator **Harkin**. Or West Germany, too, of course.

Senator **Bumpers**. The Germans say the reason they are not going to have it is because it is going to drop on Germans.

Senator **Harkin**. Or now Poland. We can actually reach into Poland. [Laughter.]

Senator **Bumpers**. They have got over $2 billion in there for the MX rail mobile garrison, and the last three Chairmen of the Joint Chiefs of Staff, the top military officers in this country for the last 12 years, all three testified we ought to torpedo that thing in a New York minute.

And Akhromeyev, who is the only guy who really has Gorbachev's ear on defense, says, why do you not offer not to build that system in exchange for our dismantling 150 of our SS-24's, which is their counterpart?

Man, I am telling you, they are not having any of that over there.

I will tell you, Dr. Raub, I hope this does not apply to you, I have a speech that I used to make, and I think I am going to start making it again. About the only way you can get people in public office to tell you the truth is in their exit interviews. [Laughter.]

Vaclav Havel is in town, and he made that magnificent speech to the Czechs on January 1. I carried it around in my speech file because it is so magnificent. He does not know anything about governing yet, but he sure knows how to put words together. And he says that his country is in a mess because for 40 years they have been saying one thing and believing another.

Tell me about it. That is what we do in this country. It is like Ronald Reagan saying I am going to double defense spending and cut taxes 30 percent and balance the budget. An old man in Arkansas said, what a dynamite idea, I wonder why nobody ever thought of that before. [Laughter.]

There was not anybody in this country who believed that. And these three Chairmen of the Joint Chiefs of Staff come in, and they said, this is nonsense.

Eisenhower gave us his military/industrial complex speech as he left office. How refreshing that would have been if he had made it in his first inaugural.

But you just simply cannot get it done.

Senator **Harkin**. Thank you for that. You are not exiting the committee right now.

Senator **Bumpers**. I am about to give you my speech. [Laughter.]

Senator **Harkin**. I am beginning to wonder what an Arkansas minute is like here, compared to a New York minute.

Dr. Raub, thank you very much for being here. Again, my thanks and esteem for your stewardship of the National Institutes of Health during this interim phase.

Dr. **Raub**. Thank you, Mr. Chairman.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

PROCUREMENT SYSTEM

Question. Since the April 1988 IG report that estimated that NIH essentially wasted $26,000,000 a year because of an inefficient and mismanaged procurement system, a number of reform efforts have been underway. These involved reducing the number of NIH employees authorized to make procurements and renegotiating many of the procurement contracts.

Last year we were told it would take several years to fully implement these reforms. What progress has been made, and when will the reforms be fully implemented?

Answer. A good deal of progress has been made on the improvement of our purchasing system. In March 1990, we are at the midpoint of our three year plan and have implemented 80 percent of its actions. While our action plan is quite comprehensive, your question centers on two of the most important aspects.

Our initial efforts in obtaining cost savings centered on renegotiating purchasing agreements with our high dollar volume vendors.

- By the end of last FY 1990 we had completed the renegotiation of 64 of the 67 agreements where our annual purchases are greater than $200,000. We are in negotiation with the other three vendors.
- This year we are concentrating on renegotiating agreements with 61 vendors whose volume of business with NIH is greater than $100,000.

Also, through an innovative purchasing approach, we are establishing competitive blanket purchasing agreements based on commodity categories (e.g., office supplies and chemicals). We hope to achieve even greater savings through this competitive process.

- By the end of fiscal year 1990, 30 commodities will have been evaluated. We anticipate 50 percent of them to be competitively solicited.
- To date, four commodities have been competed and three are in process. Discounts achieved average 20-30 percent off list price.

Through both of these efforts and through other innovative purchasing approaches that we are developing, we will be able to take advantage of potential volume discount savings even through individual orders will be of relatively low dollar value. Accordingly, the FY 1991 budget assumes a savings of $3.2 million above the savings achieved in 1989 and 1990. It should be noted that the Inspector General in subsequent reports, revised the savings potential to be between $13.6 to $21.1 million. Total savings estimated to be achieved by NIH are expected to be within this range.

With regard to restructuring the ordering offices, the objective was to substantially reduce the number of people who were involved in this activity and to ensure that they were full-time and fully trained purchasing specialists. Most Institutes have completed the restructuring and the results are impressive:

- The number of ordering officials are being reduced by about two-thirds - a reduction of over 400 individuals involved in the purchasing process.
- The number of approving officials - those who can authorize the purchase - are being reduced by over 40 percent.

These efforts should provide a more cost efficient system without an unacceptable reduction in responsiveness. The following data illustrates the impact of the restructuring:

	NIH DELPRO NODE REORGANIZATION		
Change	Before	After	%
Ordering Offices............	179	115	-36
Ordering Officials..........	635	214	-66
Approving Officials.........	200	115	-43
Subtotal..................	835	329	-61

EXTRAMURAL CONSTRUCTION

Question. Again this year NIH has not requested any funding for extramural construction. Dr. Raub, what is your view with regard to the role, or the desirability, of NIH funding for extramural construction on an ongoing basis?

Answer. NIH is aware of the need for replacement of deteriorating research facilities, as well as for new construction, to meet contemporary research needs. Within the constraints of the current budget situation, however, a lower priority must be afforded to the support of an ongoing extramural research construction program.

NIH CONSTRUCTION

Question. I see that you requested $72.1 million for a series of repair, improvement, and construction projects on the NIH campus, including an additional $16.5 million for AIDS related buildings and facilities projects, also on the NIH campus.

Dr. Raub, what can you tell us about the priority of these various projects? Which do you view to have the highest priority?

Answer. The NIH has buildings in serious need of repair and an infrastructure supporting its facilities that is short of capacity and increasingly subject to catastrophic failure. Some of our laboratories and patient care units do not provide adequate safety and many animal facilities need to be upgraded to meet the standards necessary for proper care and use of animals. In addition, renovation or construction is necessary to ensure safe, effective facilities for AIDS research.

All of the projects identified in our 1991 Buildings and Facilities request are important and are listed in priority order.

NATIONAL INSTITUTES OF HEALTH
PRIORITY CONSTRUCTION REQUIREMENTS
(Dollars in Thousands)

Project	Total Requirement*	FY 1991 Request	Portion Not Yet Funded
Repairs & Improvements	ONGOING	$ 6,900	ONGOING
NIH Infrastructure Modernization & Improvement Prog.	$ 150,000	19,200	$ 138,000
Clinical Center Modernization/Safety	40,000	14,500	25,500
Laboratory Building Renovation Project	65,000	13,000	52,000
Upgrade of Intramural Animal Facilities	45,000	18,500	26,500
AIDS Facilities	78,000	16,500	61,500
TOTAL	$378,000	$88,600	

*Estimates in 1991 Dollars

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

RESEARCH CENTERS FOR MINORITY INSTITUTIONS

Question. Are NIH and Congress aware of the impact of the RCMI Program? What are the plans for continuing the program?

Answer. The early impact of RCMI support is significant and very encouraging. A midcourse assessment of the first seven RCMI grantees, by an *ad hoc* review group, found that grant awards had had a major impact on faculty research productivity during the first three years of the RCMI Program, as evidenced by the number of publications and research grants. RCMI awards assisted faculty who utilized RCMI resources to publish a total of 775 peer reviewed scientific manuscripts; and a total of 479 research grant/contract awards were obtained. Two of the grantee institutions initiated new Ph.D. Programs, one in physiology with an emphasis in the neurosciences, and the other broadly based in the biomedical sciences.

Some examples of scientific advances resulting from RCMI support are:

- o Data acquired, in part utilizing RCMI-supported resources, was used to evaluate the appropriateness of the rat cerebral vasculature as a model for studying the pathophysiology of stroke in humans.

- In an article published by faculty at Hunter College in New York in Cancer in 1987, investigators at Hunter College, utilizing resources that are provided through the RCMI award, have shown that the hepatitis B virus (HBV) DNA integrates into human cellular DNA during long-term persistent infections.

- At the Morehouse School of Medicine, published studies indicate that human retinal pigment epithelium can be grown on collagen cells. The immortalization of these cells is now being used to determine how the human immunodeficiency virus (HIV) modulates the expression of the CMV virus, a major causative agent of blindness in AIDS patients.

Our plans are to continue support for productive RCMI programs. Currently, we are reviewing renewal applications from the first seven grantees. The anniversary date for these current awards is September 30, 1990.

Question. To what extent has this occurred both within the Division of Research Resources/Division of Research Services and the other Institutes at NIH?

Answer. As a part of the continuing efforts to apprise the Institutes, Centers and Divisions (ICD's) of the unique contributions that the RCMI community can make in the biomedical research enterprise, staff of the RCMI Program addresses the ICD Advisory Councils and participates in planning forums. Additionally, staff from several ICDs, including the National Center for Research Resources, have attended and participated in a number of symposia sponsored by RCMI grantee institutions.

Question. Does NIH plan to use RCMI eligible institutions in conducting clinical trials, especially for AIDS?

Answer. Two recent initiatives by NIH will facilitate the participation of RCMI institutions in clinical trials. One of these is a new initiative in the National Institute of Allergy and Infectious Diseases (NIAID) entitled "AIDS Clinical Trial Infrastructure Grant for Minority Institutions" which was recently announced. This initiative is intended to expand the forty-seven AIDS Clinical Trials Groups (ACTG) to include 4-5 minority medical schools. These ACTGs evaluate new therapies and methods to restore immune function and treat opportunistic infections associated with AIDS. Long-range, the intent is to increase the number of minorities enrolled in clinical trials to reflect their representation in the national demographics for this disease.

This NIAID initiative will assist these institutions to develop in three years an AIDS Clinical Trials Unit infrastructure and to acquire sufficient expertise in clinical trials for successful submission of a cooperative agreement to participate in ACTG research.

A similar endeavor has also been initiated by the Division of Cancer Prevention and Control of the National Cancer Institute (NCI). The goal here is to establish a cancer control effort which is designed to link physicians involved in care of minority cancer patients to the NCI clinical trials.

Question. What are the current NIH plans for involving the RCMI community in planning and participating in the human genome initiative?

Answer. Human genome research requires very sophisticated equipment and large groups of highly specialized scientists and technicians. Currently, human genome research is being conducted primarily at our major research institutions and large biotechnology companies. It is at places such as these that the critical mass of people and research infrastructure are found that can move the human genome program forward at an optimal rate.

The National Institutes of Health recognizes that historically black colleges and universities are placed at a disadvantage due to inadequate infrastructure and is trying to address this problem through several programs. The Research Centers in Minority Institutions (RCMI) Program is specifically designed to assist minority institutions in developing their research infrastructure. The Minority Biomedical Research Support (MBRS) Program actively promotes and supports the participation of minority institutions in biomedical research.

Discussions are now underway between the RCMI Program and the National Center for Human Genome Research to explore how minority institutions can participate in the human genome project and make use of the information produced by it. The National Center for Human Genome Research is determined to find ways to involve all groups in the human genome project itself and its long-range applications.

Question. What advantage will these administrative moves have to offer the RCMI programs in their efforts to assume a leadership role for minorities?

Answer. Since its inception, the RCMI Program has been administered on behalf of the Office of the Director, NIH by the Division of Research Resources. The movement of the RCMI Program budget into the appropriation of DRR - which has now been merged with the Division of Research Services to form the National Center for Research Resources (NCRR) - will afford the RCMI Program the opportunity to be represented more fully on the National Advisory Research Resources Council. This will enable the RCMI Program to receive full council attention in forward planning to meet the needs of the community. Additionally, we expect to establish a program advisory/initial review committee that will also provide substantive inputfrom the RCMI grantee community, as the NCRR plans for broader participation of those institutions in all of the Center's programs.

Question. Are there plans at NIH to include RCMI awards as part of the formula for the BRSG program?

Answer. The RCMI Program addresses a number of institutional needs, including the purchase of state-of-the-art research equipment, facility development, and faculty expansion and development. In addressing this latter institutional need, RCMI applications include individual research projects that are peer reviewed. These projects are investigator-initiated research projects and, therefore, are no different than many of the grants that currently make up the BRSG entitlement base. Therefore, we intend to propose the inclusion of the RCMI awards (up to $500,000 direct costs) to the BRSG Advisory Committee and the National Advisory Research Resources Council. We will seek their concurrence to include the RCMI Program award as apart of BRSG eligibility in FY 1991.

Question. Will planning grants be available for this purpose and be incorporated into the funding mechanisms of the RCMI program?

Answer. Planning grants are allowable costs within RCMI awards. RCMI is now working with an ad hoc group of RCMI Program Directors to develop the appropriate configuration of such costs in order to facilitate the development of collaborative efforts between RCMI institutions and nearby centers of biomedical research excellence.

Question. Will the proposed increase in FY 1991 be adequate to support quality applications from other eligible institutions and has the program sufficient staff to accommodate the program needs?

Answer. We believe the proposed FY 1991 budget for the RCMI Program will provide adequate resources to meet the needs of the current grantee community and will also be adequate to support quality applications from 2-3 other eligible institutions.

We are in the midst of hiring additional staff for both the RCMIProgram and the NCRR Office of Review. The RCMI Program Office will be staffed by four fulltime persons and staff in supporting offices will be increased as needed.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

DOWNWARD NEGOTIATIONS

Question. Dr. Raub, does the President's budget include sufficient funds to support continuing grants and center grants at their fully approved level? If not, what is the estimated downward negotiation rate for research project grants and center grants? How do these rates compare with FY 89 and FY 90? How do they vary Institute by Institute?

Answer. The President's budget does not support noncompeting grants, competing grants or center grants at their fully approved levels. For noncompeting grants aggregate downward negotiations from approved levels for FY 1991 will approximate 10 percent, for competing grants 14 percent and for centers 17 percent. The following table shows downward negotiation rates for noncompeting and competing research project grants and for centers.

DHHS - NATIONAL INSTITUTES OF HEALTH

FY 1989 - 1991 PERCENTAGE DOWNWARD NEGOTIATIONS

ICD	COMPETING RESEARCH PROJECT GRANTS			NONCOMPETING RESEARCH PROJECT GRANTS			CENTERS		
	FY 1989	FY 1990	FY 1991	FY 1989	FY 1990	FY 1991	FY 1989	FY 1990	FY 1991
NCI	-13.5	-10.2	-20.0	-1.6	-4.7	-4.0	-2.6	-7.6	-2.3
NHLBI	-11.5	-13.9	-13.9	-13.3	-14.5	-11.0	-10.4	-17.9	-24.4
NIDR	-10.6	-15.0	-15.0	-13.7	-12.0	-12.0	-10.0	-15.0	-16.3
NIDDK	-10.5	-12.0	-10.9	-10.5	-12.0	-10.9	-21.0	-25.0	-30.0
NINDS	-10.6	-17.4	-25.1	-8.0	-11.1	-12.0	-8.2	-16.6	-18.0
NIAID	-10.0	-12.0	-10.0	-12.0	-12.0	-10.0	-12.0	-23.0	-23.0
NIGMS	-10.6	-12.4	-12.7	-10.2	-11.2	-12.7	-8.5	-6.4	-6.9
NICHD	-14.0	-12.0	-12.0	-10.8	-15.0	-15.5	-13.6	-17.1	-21.6
NEI	-10.0	-11.0	-10.3	-8.8	-11.0	-10.3	-11.0	-30.0	-30.0
NIEHS	-11.8	-9.7	-7.3	-8.3	-8.3	-5.0	-8.5	-8.7	-13.4
NIA	-10.0	-15.4	-10.4	-12.5	-13.0	-10.5	0.0	-17.8	-21.4
NIAMS	-12.0	-12.2	-11.5	-11.9	-12.0	-11.8	-14.0	-15.0	-17.0
NIDCD	-10.0	-10.6	-8.0	-10.0	-9.3	-9.0	-10.0	-14.0	-17.5
DRR	---	-10.1	---	---	---	-10.1	-15.2	-16.0	-17.7
NCNR	-10.0	-12.3	-16.5	-11.1	-11.8	-17.0	0.0	-8.4	-9.3
NCHGR	---	-9.5	-10.4	---	-4.8	-5.0	0.0	-10.0	-10.0
NIH AVERAGE	-11.4	-12.5	-14.4	-9.5	-11.1	-10.1	-11.4	-15.5	-17.3

BIOMEDICAL RESEARCH

Question. Dr. Raub, what was the original NIH budget request submitted to the Public Health Service for FY 1991? How does it compare with the request for the NIH in the President's budget? How much would be required to keep pace with the biomedical research inflator?

Answer. The original FY 1991 budget request submitted to the Public Health Service totaled $11,058.5 million. This amount is $3,128.8 million more than the President's budget request.

The estimated FY 1991 Biomedical Research and Development Price Index (BRDPI) is 5.8 percent. If the BRDPI was applied to the FY 1990 budget, excluding funding for AIDS, the Human Genome Program, and B&F, since these programs have increased by a higher rate than the BRDPI, the FY 1991 estimate would be $7,103 million. This is an increase of approximately $170 million over the budget request. When you add back funding for AIDS, the Human Genome Program, and B&F, the total estimate is $8,100 million.

CHANGES IN EASTERN EUROPE

Question. Dr. Raub, what impact, if any, will the recent changes in Eastern Europe and the Soviet Union have on the National Institutes of Health activities in the coming fiscal year? What opportunities do these events afford for improving the stability and quality of life in both the United States and these nations? Does the President's budget for fiscal year 1991 include additional funds for expanded outreach and collaboration with the biomedical research scientists in Eastern Bloc nations?

Answer. Early indications show that several of the Institutes, Centers and Divisions of NIH will attempt to expand their collaboration with East European and Soviet scientists in light of recent political changes. We also expect Eastern European scientists to participate more fully in the ongoing Fogarty International Center-administered scientist exchange programs. The President's budget for FY 1991 for the Fogarty International Center includes an additional $50,000 targeted for expanded collaboration with East European and Soviet biomedical research scientists.

Some research opportunities the NIH has identified include the following.

- Research on Cardiovascular and Pulmonary Disease--while cardiovascular disease has declined by 35% during the last two decades in the U.S., it has risen by 60% in Poland. Hungary has the highest rates in the world for bronchitis, emphysema and asthma.

- U.S. and Czechoslovakian scientists have proposed research on ischemic heart disease and other pulmonary and blood disorders; U.S. and Romanian scientists have prepared symposia on similar subject areas.

- NIH scientists are interested in studying the health effects of toxic chemicals and other environmental pollutants and in assisting researchers in Eastern-Europe to monitor dangerous chemical levels.

- Lyme Disease is of special interest to U.S. researchers because the tick species responsible for its transmission in Europe is different from the U.S. species. Dermatological and neurological complications seem to be more common in Europe and insights into the natural progression of the disease could be forthcoming from cooperative research.

- AIDS research is a priority throughout eastern Europe. HIV infection rates and demographics that differ from the U.S. experience have prompted considerable interest. The problem of pediatric AIDS is particularly acute in Romania.

- U.S. scientists are eager to expand ongoing collaboration with the Institute for Mother and Child in Poland.

- In the Cancer area, the Soviets are interested in establishing cancer centers based on the U.S. model. We are supportive of this effort and of sharing cancer data with Soviet medical practitioners and scientists.

- Dental research, brain function research, neurobiology, biomedical engineering, genetic research and mathematical modeling are also areas where mutual interests have been expressed.

In order to take advantage of these and other research opportunities in the region, the Fogarty International Center has developed a proposal for an Eastern European Initiative, which could also be expanded to include the Soviet Union. The Initiative, for which funds are not included in the FY 1991 budget request; would provide the following:

- Research grants for U.S. scientists to conduct collaborative research with Eastern European scientists (26 grants at $50,000 each for a total of $1,300,000). American scientists who already have research grant support from NIH will be invited to apply for these grants through the regular NIH grants review process. These grants will cover additional costs of conducting research in the American scientist's laboratory in cooperation with an Eastern European scientist and will provide for supplies and equipment needed by the Eastern European scientific collaborators (most of which would be purchased in the West). These grants would also pay for scientific exchanges so that the investigators in both countries can work together. Topics covered by these research grants would include cancer, cardiovascular disease, influenza and virus diseases, neurological disorders, environmental health, aging, and other scientific areas of high mutual priority.

- Training grants in U.S. institutions for Eastern European scientists and health professionals involved in the scientific and medical aspects of AIDS (20 trainees at $30,000 each for a total of $600,000). These grants would supplement existing international AIDS training grants already awarded by the Fogarty International Center to ten U.S. universities.

- Research fellowships to support Eastern European scientists in U.S. biomedical research laboratories (40 fellowships at $30,000 each for a total of $2,300,000). These fellowships would be offered through the Fogarty International Center's International Research Fellowship Program which supports young scientists for one to two years for training. These additional funds would enable FIC to respond to requests from Bulgaria and Czechoslovakia and would expand the program in other Eastern European countries.

- Short-term exchange research consultations between U.S. and Eastern European scientists (50 exchange visits at a cost of $8,000 each for a total of $400,000). The travel and per diem for Eastern European and American scientists to undertake collaborative research consultations in each other's countries for periods of up to six months.

- Scientific workshops (10 workshops at a cost of $50,000 each for a total of $500,000). These funds would support technical workshops or conferences designed to bring together individuals with common scientific interests to exchange information, develop linkages and define areas of promising scientific collaboration between scientists and institutions in both countries.

NATIONAL CANCER INSTITUTE

STATEMENT OF DR. SAMUEL BRODER, DIRECTOR

BUDGET REQUEST

Senator HARKIN. We now want to call up our panels.

We will start first the panel with Dr. Samuel Broder, Director of the National Cancer Institute; Dr. Claude Lenfant, Director of the Heart, Lung, and Blood Institute; Dr. Harald Löe, Director of the National Institute of Dental Research; Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, and Associate Director for HIV Research at NIH.

And we will go in the order in which I called, and not necessarily in any order of importance or priority, but this is the way my book is organized. So we will start with the National Cancer Institute.

Dr. Broder, we are glad to have you with us this morning. Your budget request is for $1.694 billion, an increase of almost $60 million over last year, and a growth rate of approximately 3.7 percent.

I also notice you intend to continue support for the 56 research centers, and your total number of research grants would be 3,109, a reduction of 10 grants from 1990.

Dr. Broder, if you would proceed with a brief statement, and then what we will do is we will take each Institute and then we will come back for general questioning for everyone.

PREPARED STATEMENT

Your statements will all be made a part of the record in their entirety. I read them over the weekend and I would just ask you to please proceed and either summarize or highlight what you want us to focus on.

[The statement follows:]

STATEMENT OF DR. SAMUEL BRODER

One million Americans will learn this year that they have cancer and about half of them will eventually die of cancer. Our best response to the challenge of cancer -- a disease which causes suffering beyond metaphor -- must be an intense effort to generate knowledge and to apply it quickly. The three foundation stones of the NCI are: basic research, clinical trials in prevention and therapy, and the cancer centers. The results of NCI's research belong to all Americans regardless of their race, age, income, social status, or place of residence.

Cancer research and technology transfer require creative, highly trained scientists and clinicians and well equipped laboratories. Other resources are needed, such as a network of cancer centers, each bringing interdisciplinary approaches to cancer in its community, as well as addressing national and regional problems. An array of organized clinical trials is needed to generate knowledge regarding new drugs, preventions, and therapies. A vigorous program of clinical trials must involve academic centers and community physicians.

Among other achievements, two NCI scientists (together with a colleague from the National Heart, Lung, and Blood Institute) made medical history last Spring by inserting new genetic material into human cells, returning the cells back to the patient, and then tracking the gene-engineered cells in the patient's circulatory system two months later. These experiments will lead to gene therapies and are based upon NCI basic research accomplishments.

Recently, NCI-supported scientists have made a number of important molecular discoveries, including: the location of molecular abnormalities believed to contribute to lung, colon and breast cancer by a loss of a critical regulatory mechanism; the location of the gene responsible for familial malignant melanoma on; identification of five proteins, implicated in the process of metastasis (the wild spread of cancer). Such discoveries pave the way for future research on prevention and cure of cancer.

For over 50 years, scientists have sought the cause of cystic fibrosis, and recently NCI-supported scientists discovered that the cystic fibrosis gene was linked to an oncogene (called met) thus providing a marker, which greatly facilitated the recent discovery and cloning of the cystic fibrosis gene.

NCI-supported clinical trials have shown that in some cancers, adjuvant treatment after surgery can reach remaining microscopic tumors, prevent tumor recurrence, and prolong or save lives. Last year adjuvant treatment using a combination of levamisole and 5-Fluorouracil, after surgery in Dukes' C colon cancer, an advanced cancer, made an improvement in 5-year survival rate, reducing deaths by a third. There will be approximately 110,000 new cases of colon cancer in 1990, of which 21,000 will be classed as Dukes' C stage.

Neoadjuvant therapy, that is using chemotherapy or radiotherapy before surgery, may shrink certain cancers and make it possible to limit surgery, permitting the salvage of structures like the bladder, rectum or breast which would otherwise have been sacrificed to stop the cancer.

Clinical trials often take years to complete. Now, in addition to large clinical cooperative groups, NCI is using the mass media to draw attention to clinical trials. Accelerated enrollment speeds evaluation of new therapies and brings state-of-the-art therapies to more people.

NCI has a long commitment to cancer prevention. Chemoprevention studies are being carried out in breast, lung, colon, bladder, and skin cancers with agents related to the retinoids, beta-carotene, vitamin E, selenium, and other substances. A recent study showed that a high wheat fiber diet decreased the number of large bowel polyps -- cancer precursors. This study was conducted in patients at high risk for large bowel cancer, but this diet may reduce the risk of bowel cancer among all Americans.

Sometimes research affects us right in our own backyards; NCI-supported scientists have studied and identified the mutagenic substances formed when meat is grilled or fried. These substances may contribute to a risk for certain cancers and a better understanding of this process should help to lessen this risk.

NCI is studying a interventions with people already at high risk. One study is testing the effect of beta-carotene and retinol for asbestos workers who are at high risk for lung cancer. Another study is evaluating the effect of dietary fiber combined with calcium in individuals who have a high risk of colon cancer.

NCI conducts national programs to educate the public about cancer, at times using innovative approaches such as working with supermarkets in minority neighborhoods to highlight food choices that may help to reduce the risk of cancer.

NCI makes state-of-the-art information available to everyone in the country through the Cancer Information Service (CIS) via its toll-free 1-800-4-CANCER number. Over 500,000 people called CIS last year. Counselors use NCI's computerized Physician Data Query (PDQ), which describes state-of-the-art cancer treatment and available clinical trials. This CIS is now reaching more states and more people than ever before.

For white Americans under 65 the death rate for certain cancers is falling. But again this year, NCI statistics show that minority groups, the poor, the underserved and those over 65, have disproportionately high rates of cancer mortality. The reasons are complex and relate in part to special problems in terms of access to state-of-the-art prevention, early detection, and treatment. In response, NCI has made reduction of cancer mortality in these populations a high priority.

NCI is publishing a new atlas of cancer mortality in nonwhite populations which shows geographic areas with high rates of cancer and this will guide epidemiologic studies and programs aimed at reduction of cancer in underserved groups. Also to this end, NCI has incorporated the National Black Leadership Initiative on Cancer which assists black community-based and national leaders in organizing programs for early detection and prevention of cancer.

Lifestyle changes, compliance with screening guidelines and smoking cessation, can prevent cancer deaths. Consequently, lung cancer deaths for men in some age groups are declining -- slowly, but surely. Lung cancer accounts for 30 percent of cancer deaths, so any reductions will make a marked impact on cancer mortality in the future. Unfortunately, we need to do more to reach women and adolescents.

Early detection of cancer saves lives and is not used to full advantage. The Pap test is widely available, yet 6,000 women die each year of cervical cancer. NCI has improved screening for cervical cancer and is working to increase its use. Breast cancer is one of the leading causes of cancer death in women with 150,000 new cases and 44,000 deaths in the United States expected in 1990 -- deaths that could be reduced by 30 percent or more if mammography guidelines were followed.

Last Fall, a Women's Leadership Summit on Mammography was held on Capitol Hill to launch NCI's National Breast Screening Awareness Campaign in an effort to reduce breast cancer deaths, by expanding mammography utilization.

Where early detection or state-of-the-art treatment programs have been established, beneficial results are seen. A report from the San Francisco/ Oakland based Surveillance Epidemiology and End Result Program shows striking changes in early breast cancer detection and a dramatic shift towards less radical surgical treatment.

Treatment research brings hope to today's cancer patient. New treatments are developed through clinical trials and where early results are promising, special interim Food and Drug Administration classifications such as the Group C mechanism allow private physicians to use the drugs for appropriate patients. This is extremely important because for some cancers experimental drugs are the only effective treatment available. The following drugs were placed in Group C status last year: levamisole plus 5-fluorouracil for adjuvant treatment of Dukes' C colon cancers; deoxycoformycin for the treatment of hairy cell leukemia refractory to the standard treatment of alpha interferon; and fludarabine phosphate for refractory chronic lymphocytic leukemia which represents a significant advance in this common kind of leukemia in adults, with about 9,600 new cases each year.

Compounds developed at NCI and recently given New Drug Approval (prescription) status include: ifosfamide, flutamide, and carboplatin for treatment of the metastatic stage of testicular, prostatic, and ovarian cancer respectively. A New Drug Approval application for fludarabine for chronic lymphocytic leukemia has been made.

NCI's research is helping to prolong survival by improving management of drug resistance which can render certain cancers impervious to chemotherapy. Agents being studied to combat drug resistance include: steroids and steroid antagonists, calcium channel blockers, cardiac antiarrhythmic drugs, immunosuppressants and monoclonal antibodies. Researchers have found that adding the drug verapamil, a calcium channel blocker used in cardiology, to the usual chemotherapy regimen reduced drug resistance in patients with refractory myeloma and non-Hodgkin's lymphoma.

An old drug, suramin, long used for treating parasitic infections, is the first drug to have been found active in treating advanced prostate cancer, which has failed conventional.

Clinical trials on breast cancer are comparing the effectiveness of tamoxifen, with and without radiation therapy, in women whose cancer has not spread to nearby underarm lymph nodes. Over 2,600 women will participate, but nearly 70,000 women have similar cancers.

A study on small cell lung cancer is comparing standard treatment (chemotherapy and a daily dose of radiation) with an experimental regimen which uses the same chemotherapy, but with smaller, more frequent doses of radiation. About 360 people will be enrolled in this study over two years, but approximately 80,000 Americans would qualify by these criteria.

A number of clinical trials are testing natural human biological substances as novel treatments. Colony stimulating factors (CSF) which originate in the bone marrow, are proving useful in some hard-to-treat childhood cancers, such as neuroblastoma and aggressive lymphoma. These factors are improving statistics for treating other cancers, e.g., breast cancer. The CSFs appear to protect the bone marrow (the site of production of blood components) during high-intensity chemotherapy.

Although not the lead NIH agency, NCI has an important role in AIDS drug and vaccine development and NCI scientists continue to investigate the pathogenesis of AIDS, the biologic mechanisms by which the HIV causes infection, immune system destruction, multi-organ system dysfunction and some specific HIV-related cancers. The NCI intramural program has emerged as one of the most important centers in the world for development of therapeutics for children with AIDS.

Last year, 16 new anti-viral drugs have moved into preclinical testing. Compounds are evaluated for activity against HIV on a high-capacity screen of cells. Since 1987, over 14,000 chemical structures have been tested, of which 70 had anti-HIV activity. It is expected that up to 100 anti-HIV compounds may be identified each year -- with only three to four compounds developed each year.

In addition, NCI continues several AIDS epidemiologic and natural history studies, both descriptive and interventional, in the United States and abroad.

This research has had encouraging results. An individual diagnosed with AIDS in 1982 had only a 30 percent chance of being alive 18 months after diagnosis. This situation improved first at the end of 1986 and then dramatically in 1987. AZT, a drug developed by NCI in collaboration with a private sector company, was approved by the FDA in March of 1987. Thus, an individual diagnosed in 1987 had a greater than 60 percent chance of being alive at 18 months.

All of us are aware of the challenge and difficulties that we face. Progress against the suffering and deaths from cancer will not be easy, but we have built a program where success is possible and the continued support evidenced by the President's Budget ensures that it will occur. Mr. Chairman, the 1991 budget request for the NCI totals $1,694,059,000. I would be pleased to answer any questions.

BIOGRAPHY OF DR. SAMUEL BRODER

EDUCATION: 1966 B.S. - University of Michigan, College of Literature, Science and the Arts, Ann Arbor, MI (high honors)
1970 M.D. - University of Michigan, Ann Arbor, MI (cum laude)

EMPLOYMENT:

1970-1971	Internship (Medicine), Stanford University, Palo Alto, CA
1971-1972	Residency (Medicine), Stanford University, Palo Alto, CA
1972-1975	Clinical Associate, Metabolism Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD
1975-1976	Investigator, Medicine Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD
1976-1981	Senior Investigator, Metabolism Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD
1981-1988	Associate Director, Clinical Oncology Program, Division of Cancer Treatment, National Cancer Institute, National Institutes of Health, Bethesda, MD
1989-pres	Director, National Cancer Institute, National Institutes of Health, Bethesda, MD

HONORS, SOCIETIES and ORGANIZATIONS:

Phi Beta Kappa
Alpha Omega Alpha
Fellow of the Life Insurance Medical Research Fund
UpJohn Achievement Award
Arthur S. Flemming Award
Public Health Service/Meritorious Service Medal
Public Health Service/Distinguished Service Medal
Thirty-seventh Augustus B. Wadsworth Lectureship
Third Mullin Lectureship/University of Scranton
Fourth Biennial Chemistry as a Life Science Lectureship/Rutgers University
Twelfth Annual CIBA-GEIGY DREW Award in Biomedical Research
Alpha Omega Alpha Distinguished Professor, Dartmouth Medical School
Robert T. Wong, M.D. Endowment Award, University of Hawaii Foundation
Samuel Rudin Award, Columbia Presbyterian Hospital
First Annual Institute of International Health & Development Award
Gilman Honors Award/New York University
Harvey W. Wiley Medal/FDA Commissioner's Special Citation
American Society for Clinical Investigation (elected 1980)
Association of American Physicians (elected 1989)
American Federation for Clinical Research (Eastern Section Councilor)
American Association for Cancer Research
American Society for Clinical Oncology
American Association of Immunologists
Clinical Immunology Society
Editorial Advisory Board for numerous journals
Editor, Symposium on HTLV, September 1985, Cancer Research
Editor, AIDS: Modern Concepts and Therapeutic Challenges
Fellow, American College of Physicians

BOARD CERTIFICATIONS and LICENSES:

1973	Certified in Internal Medicine
1977	Certified in Medical Oncology
	Licensed to practice Medicine in California and Maryland

MAJOR PROFESSIONAL INTERESTS: Relationship between cancer and immunodeficiency states; anti-retroviral chemotherapy

OPENING REMARKS

Dr. **Broder**. Sir, with your permission, I would read a very brief statement.

I would like to thank the distinguished chairman and distinguished members of the committee for the opportunity of being here. Our best response to the challenge of cancer, a disease which causes suffering and death beyond metaphor, must lie in an intense effort to generate knowledge and to apply it quickly.

In doing so, we rely on the three foundation stones of the National Cancer Institute, which are, one, basic research; two, clinical trials in prevention and therapy; and three, the cancer centers.

The NCI is committed to extend the results of its research to all Americans regardless of their race, age, income, social status, or place of residence.

Again, this year, NCI cancer statistics show good news and bad news. The bad news is that minority groups, the poor, the underserved and those over 65 have disproportionately high rates of cancer, and consequently, these groups are targeted for our priority attention.

The good news is that for white Americans under age 65, death rates have clearly declined in certain common cancers. Thus, while we have made progress, more progress is needed.

Science underlies every aspect of the NCI program, and this year, among other scientific achievements, two NCI scientists, together with a colleague from the National Heart, Lung, and Blood Institute, made medical history by inserting new genetic material into human cells, and putting said cells back into a patient's body.

These experiments presage future therapies, and are the legacy of prior NCI basic research on natural body mechanisms for fighting cancer.

Recently, NCI-supported scientists have made a number of important genetic discoveries, including the location of molecular abnormalities, which contribute to the development of lung cancer, colon cancer, breast cancer, and prostate cancer.

In addition, NCI-sponsored research has developed the location of the gene for familial malignant melanoma, and has identified specific genes implicated in the metastatic process, the process by which cancer cells spread widely.

There is major progress in practical cancer treatment. Clinical trials have shown that in some cancers, what are called adjuvant treatments, that is, chemotherapy after surgery, can eliminate remaining microscopic tumors.

Last year, an adjuvant treatment for one stage of colon cancer was shown to make an improvement of approximately one-third in the death rate of that particular disease.

Prevention trials are also a very high priority. For example, NCI is studying interventions for individuals already at high risk of cancer. And one study is testing the effect of beta-carotene and retinol, substances which might be used for the treatment of asbestos workers who are at high risk for lung cancer.

A recent NCI prevention study showed that a high wheat fiber supplement decreased the number of large bowel polyps, which are precursors to cancer of the large bowel.

And of course, we are continuing programs to reduce smoking.

The NCI cannot do its job from an ivory tower, and thus NCI reaches out to the public to provide information about reducing death and suffering from cancer.

Last year about 19 million cancer information publications were mailed to the general public. And about 500,000 people called our cancer information CIS telephone service, which has a toll free number for personal answers to their questions. The Cancer Information Service [CIS] uses the NCI's most recent electronic databases to describe state-of-the-art cancer treatment and clinical trials.

Screening and early detection are also very important. Thus, breast and cervical cancer are diseases where deaths could be reduced by more widespread screening for early detection. More than 6,000 women die each year of cervical cancer; most could have been saved with early PAP tests.

There will also be approximately 150,000 new cases of breast cancer, and we believe that there will be approximately 44,000 deaths. The death rate could perhaps be reduced by 30 percent or more if physical exam and mammography guidelines were followed.

Last fall, a women's leadership summit on mammography was held on Capitol Hill to launch the NCI National Breast Cancer Screening Awareness Campaign. This was an important initiative, with Mrs. Bush as the keynote speaker.

Finally, future therapies will depend on a program of new drug development. The NCI is a national resource for such new drug development. A number of experimental drugs last year were introduced and were made available to the public at large.

In some cases, the only available treatment for a cancer represents these experimental drugs.

New drug approval status was given to drugs for advanced stages of testicular, prostatic, and ovarian cancer, and also for chronic lymphocytic leukemia.

We expect to continue this momentum for the future.

Mr. Chairman, the 1991 budget request for the National Cancer Institute totals $1.694 billion.

I would be pleased to answer any questions.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. Dr. Broder, thank you very much. That was a succinct, yet enlightening statement. I appreciate that very much.

There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

CANCER DEATH RATES

Question. Since 1971 when President Nixon declared war on cancer we have spent approximately $16 billion on cancer research. In the 1990s I expect we will spend at least that amount on cancer research.

In spite of this level of spending the overall deaths from cancer increase each year, while the rates from other major causes of death decline. In 1950, cancer caused 15 percent of all U.S. deaths; in 1985, 24 percent. Although some of the increase is due to an aging population, even the age-adjusted cancer mortality continues to climb. Incidence and death rates for those under and over 65 are on the rise. Dr. Broder, what are the cancer death rates for those both under and over 65?

Answer. The age-adjusted (1970 U.S. standard) cancer mortality rates for 1983 to 1987 are:

- 75.7 per 100,000 persons less than 65 years of age
- 1,040.5 per 100,000 persons 65 years and older.

The corresponding age-adjusted (1970 U.S. standard) cancer incidence rates for 1983 to 1987 are:

- 189.8 per 100,000 persons less than 65 years of age
- 1,983.3 per 100,000 persons 65 years and older.

Question. Are we making progress?

Answer. National mortality trends demonstrate significant improvements in certain age groups and cancers, although for others, there remains an increasing cancer burden.

It is estimated that over one million Americans will be diagnosed with cancer in 1990, and approximately 500,000 people will die of cancer during this year. These projected estimates reflect the increasing number of older Americans in our population. Statistics show that these older Americans have a higher risk of developing the disease, as one-half of all cancer cases occur in persons age 67 and over.

While overall the number of deaths and the cancer mortality rate have increased between 1973 and 1987, a closer look reveals that mortality rates have shown substantial declines for persons under age 65. This is especially true for children, for whom cancer mortality has dropped 36 percent.

These significant improvements in cancer mortality occurred despite a persistent increase in the rate at which individuals develop cancer. The cancer incidence rate for all cancers combined increased by 14.6 percent between 1973 and 1987, while the overall cancer mortality rate rose by only 5.4 percent over the same time period.

Some highlights of the progress are detailed below:

Under Age 65

- The mortality rate for all cancer sites combined has declined for both males and females under the age of 65 between 1973 and 1987.

- Cancer mortality in children has declined 36 percent in the 15 years between 1973 and 1987. This progress is attributable to treatment advances, particularly those developed through the Nation's network of clinical trials and cancer centers.

- With the exception of children under age five, the annual decline in the overall cancer mortality rate for each age group under age 55 was greater from 1975 to 1987 than during the previous 25 years, 1950 to 1975.

- When lung cancer is excluded, the mortality rate for all other cancer sites combined has declined for both males and females under the age of 65 throughout the 15-year period of 1973 to 1987.

- Significant reductions can also be seen in the annual cancer mortality rates for various cancers among persons under age 65. For example, bladder cancer mortality has decreased 32 percent; ovary, 25 percent; colo-rectal cancer, 15 percent; oral cancer, 20 percent; cervical cancer, 39 percent, and corpus uteri, 37 percent. These are not rare cancers. Nevertheless, other cancers have shown increases: lung and bronchus, 15 percent; melanoma, 16 percent; multiple myeloma, seven percent; and esophageal cancer, five percent. Between 1973 and 1987, the overall mortality rate for all cancers combined for persons under age 65 decreased 4.5 percent.

Over Age 65

- For persons ages 65 and older, the overall cancer rate has increased. Nevertheless, many prevalent cancers have shown significant declines. These include colo-rectal cancer, seven percent; bladder cancer, 20 percent: and cervical cancer, 40 percent. For other sites there has been an increase in mortality, including: all sites combined, 13 percent; lung cancer, up 53 percent; melanoma, 55 percent; brain cancer, 58 percent; non-Hodgkin's lymphoma, 40 percent; multiple myeloma, 33 percent; breast cancer, 12 percent; and prostate cancer, eight percent.

Minority Populations

Black Americans continue to experience a disproportionate cancer burden. Black males have an overall mortality rate that is approximately 40 percent higher than that of their white counterparts. This is especially true for esophageal cancer where the mortality rate for Black Americans is three times the mortality rate for whites. The overall mortality rate for Black women, while not as high as that for Black men, is nevertheless about 20 percent higher than that experienced by white women.

In 1987, the mortality rates were 213.4 per 100,000 for white males and 138.1 per 100,000 for white females. In contrast to these figures, the mortality rate for Black males was 299.8 per 100,000 and for Black females, 162.7. Similar race-sex differences were also noted for cancer incidence rates.

In some instances, Black rates have been shown to be increasing for the same cancers for which mortality rates are falling among whites. For example, whites have experienced an 11 percent decrease in mortality from colo-rectal cancer. In contrast to this, the Black mortality rate has actually increased 10 percent for this same cancer between 1973 and 1987.

The differences between five-year relative survival rates among Black and white Americans is particularly striking: 57 percent for white females as opposed to 44 percent for Black women, and 47 percent for white males as against 33 percent for Blacks.

In summary, the data show a profile of both progress achieved and the challenges that remain. Mortality rates are decreasing for persons under age 65 for all cancer sites combined as well as for a large number of common specific cancers. Yet, for other cancers in this age group, mortality rates are on the rise, and the same decline seen in cancer mortality rates for those under age 65 cannot be demonstrated in persons over age 65.

Decreases in diseases like colo-rectal cancer, bladder cancer, children's cancers, and a number of other cancers, all demonstrate that prevention and early detection combined with treatment can effectively reduce cancer mortality. On the other hand, experts have watched with considerable dismay as death from lung cancer continues to climb among women, despite all that is known about preventing this disease. For women, lung cancer mortality has finally overtaken breast cancer as the leading cancer killer. From 1973 to 1987, the death rate for female lung cancer rose by more than 100 percent. It is clear that we must continue to focus our efforts on the prevention of cancers such as lung and melanoma which have shown a rapid increase, and those cancers such as breast for which early detection (e.g., routine breast physical exam and low dose mammography) has been shown to significantly reduce cancer mortality. Through a variety of efforts in both prevention and treatment research, NCI is confident that the progress that has been achieved to date against cancer mortality will continue and that new inroads can be made to reduce the disproportionately high rate of cancer mortality rates experienced by Black and older Americans.

Question. For the first time more women are dying of lung cancer than breast cancer. Does this suggest the need for a greater stop smoking campaign focused on women?

Answer. Our most recent mortality figures come from the Surveillance, Epidemiology and End Results (SEER) data base in 1987. More women died from lung cancer in 1987 (42,700) than any other single cancer site, including breast cancer (40,900); and according to the American Cancer Society projections for 1990, lung cancer in women will account for 50,000 deaths or about 6,000 more than from breast cancer. Lung cancer has been the single leading cause of cancer deaths in men for nearly 40 years. It makes us very sad, indeed, that women have now achieved a kind of parity with men in this area.

The National Cancer Institute has recognized the special need to address the apparent difficulty in getting women to stop smoking. Since 1985, NCI has funded 11 intervention trials focused exclusively on women. Some of these trials target cessation and maintenance efforts for low-income, predominately black, and pregnant women. In addition to these 11 trials, the NCI supports 50 other cessation or prevention trials, all of which include, but do not focus exclusively on, adult or adolescent females.

In 1987 the NCI convened a workshop of the Nation's smoking control leaders to establish a women's network to actively counter the cigarette industry's increasing marketing and promotion activities directed toward women. The "Not Far Enough: Women versus Smoking" network is composed of individuals representing 24 national women's health, research and academic institutions across the country. This network was instrumental in identifying the R.J. Reynolds "Dakota" cigarette marketing strategy aimed at young "virile" women which was strongly criticized by Secretary Sullivan.

In further recognition of the need to reach women smokers, NCI, in conjunction with the American Cancer Society, is conducting the American Stop Smoking Intervention Study for Cancer Prevention (ASSIST). This demonstration project specifically identifies women and adolescent females as high priorities for both smoking cessation and prevention activities. It is planned that ASSIST will reach a minimum of 35 million adults and nearly six million adolescents in 16 sites representing entire states or large metropolitan areas by 1993. Approximately half of these individuals will be women. Intervention strategies and channels to reach large numbers of women and adolescent females include the health care system, schools, the media, worksites, public policy, and community organizations and networks.

Funding for the ASSIST project is estimated at $1.6 million for FY 1990 and approximately $7.1 million in FY 1991. The 18 to 24 month planning phase will be followed by implementation of these plans over the course of the next decade. The overall cost of the ASSIST project is estimated to be $96 million through the year 2000.

CANCER PREVENTION INFORMATION

Question. Dr. Broder, as you have told the committee in the past, a great number of cancers can be successfully treated and perhaps avoided by early detection and treatment as well as by diet and lifestyle changes.

In FY 1990 NCI expects to spend $92,000,000 on information dissemination; the FY 1991 budget includes $94,000,000 for information dissemination.

The Committee was disappointed that NCI was not able to spend $96,000,000 in FY 1990 as we had recommended.

In your professional judgement what should we spend for this purpose in FY 1991?

Answer. I wish to thank the Chairman and members of this committee for their interest in our cancer information activities. The Institute is very committed to information dissemination. We have been able to provide a significant expansion of our cancer information activities -- nearly a $4 million increase over the level funded in 1989. Included within this increase, as directed by the Senate in Report language, is $900 thousand for the Cancer Information Service. The FY 1990 level of $92.3 million represents a compromise amount, based on House/Senate passed levels, as well as the impact of sequestration and other assessments. Even with reductions, information dissemination increases 4.5 percent, or nearly the five percent referenced in the Senate Report, over NCI's FY 1989 level of $88.6 million. The NCI is giving special attention in supporting activities such as our Cancer Information Service. This service provides direct information about state-of-the-art developments directly to patients and their families throughout the country.

The professional judgement need for information dissemination is, in part, dependent upon the total resources available to the Institute, as a balance of program support is needed to permit the further development and discovery of research results before they can be transferred to the public and professional communities. Within the FY 1991 By-Pass level of $2.4 billion, additional resources were included for outreach activities through the cancer network, including cancer centers, clinical trials and cancer prevention and control research. As a corollary to these outreach arms, information dissemination would have been established at approximately $132 million. However, I would like to stress that our professional judgement regarding resources needed for information dissemination couples this need to the total funds available for the National Cancer Institute. In my professional judgement, it would be desirable to continue this linkage.

DRUG DEVELOPMENT

Question. Dr. Broder, as you know, there are now 34 drugs in clinical trials in the AIDS program. How many drugs are in clinical trials in the cancer program?

Answer. There are a large number of agents that are currently in clinical trials that are being tested for their efficacy not only in the treatment of cancer, but in the prevention of cancer as well. Overall, there are 125 cytotoxic and 60 biological agents in clinical trials for the treatment of cancer, and 15 drugs in clinical trials for the prevention of cancer. Biologics and natural products are becoming more and more important. Attached is a listing of these agents.

CANCER TREATMENT DRUGS

BIOLOGICAL RESPONSE MODIFIERS

PHASE I

Auto. Tumor Vaccine/BCG (Tice)
CSF-G (Amgen)
CSF-GM (H)/Yeast
CSF-GM (H)/E. Coli
CSF-M (Cetus)
FAA
IFN: Beta (Mochida)
IL-1 Beta (Syntex)
IL-1 Alpha (Dia)
IL-2 (Cetus)/BCG (Tice)/TCV
IL-2 (Cetus)/IL-4 (Sterling)
IL-2/A-LAK (Cetus)
IL-2/AEL (HLR)
IL-2/MDELAK (Cetus)
IL-2/TIL (Cetus, biorector expanded)
IL-2/TIL (Cetus)
IL-2/TIL (HLR)
IL-3
IL-4
MoAb: TAC-PE Conjugated
MoAb: TAC
MoAb: Carcinoma (B72.3)
MoAb: OVB-3-PE
MoAb: OKT-3
MoAb: Lym-1
MoAb: 14G2A
MoAb: Melanoma (9.2.27)
MoAb: XomaZyme-H65
MoAb: L6
MoAb: BL3-GD
MoAb: HeFi-1
MoAb: Bombesin (2A11)
MoAb: CC-49 (Dow)
MoAb: IMMU-4
MoAb: T-cell (3A1, 95-5-49, 95-6-22)
MoAb: Colorectal (LiCo 16.88, 28A32)
MoAb: Chimeric B72.3
MoAb: B72.3 Chimeric gamma-1
N2 transduced lymphocytes
N2 transduced TIL
TNF (Cetus)

PHASE II

(IFN: Rec Gamma (Schering))
cis-Retinoic Acid
GSF-GM (Schering)
IFN: Rec Beta (Triton)
IFN: Rec Gamma (Biogen)
MoAb: ^{111}InT101IL-2 (HLR)
MoAb: R24
MoAb: Colorectal (17-1A)
Poly ICLC
TNF (Genentech)

PHASE II-III

BCG (Connaught)
BCG (Tice)
IFN: Rec Alpha 2 (Schering)
IFN: Lymphoblastoid (BW)
IFN: Rec Leukocyte A (HLR)
IFN: Rec Gamma (Genentech)
IL-2 (Cetus)
Levamisole

OTHER

Hydrazine Sulfate

CYTOTOXIC AGENTS

PHASE I

BSO
CQS
Deoxyspergualin
Dihydrolenperone
Fazarabine
Fostriecin
Hepsulfam
Hycamptamine
Ipomeanol
Lip-encap dox
Mafosfamide
Piroxantrone
Porfiromycin
Pyrazine diazohydroxide
Terephthalamidine
Teroxirone
Tetraplatin
Uridine

PHASE II

(DCMTX)
10-EDAM
6-MMPR
6-TG
Aclacinomycin
AT-125
ATDA
Bisantrene
Caracemide
Deazauridine
DFMO
DHAC
Didemnin-B
Echinomycin
FAMP
HHT
HMBA
Merbarone
NMF
Pibenzimol
Spirogermanium
Spiromustine
Suramin
Taxol
TCNP
Tiazofurin
TMCA
TMTX

PHASE II-III

(Streptozotocin)

6-MP (PO)
6-MP (IV)
Amonafide
AMSA
Azacytidine
AZQ
CBDCA
CHIP
Chlorozotocin
DBD
Deoxycoformycin
Flutamide
HDMTX
HMM
Ifosfamide/Mesna
Leuprolide
Melphalan
Menogaril
Methyl CCNU
Methyl G
Mitoxantrone
PALA
PCNU
Thymidine
TZT
VM-26
Zoladex

OTHER

AZT
AZT/Acyclovir/ddI/ddC
BUdR
ddC/AZT
ddI for hepatitis
Dideoxyadenosine
Dideoxycytidine
Dideoxyinosine
Erwinia asparaginase
Gallium Nitrate for hypercalcemia
and bone loss
ICRF-187
IUdR
Leucovorin (PO)
Leucovorin (IV)
Miso (IV)
Photofrin
SR 2508
TMTX for AIDS
WR-2721

COMMERCIALLY AVAILABLE AGENTS

BCNU (Carmustine)
Bleomycin
Carboplatin
Chlorambucil
Cisplatin
Cyclophosphamide
Cytarabine (ARA-C)
Dacarbazine (DIC)
Dactinomycin
Daunomycin
Doxorubicin
Fluorodeoxyuradine
Fluorouracil (5FU)
Flutamide
Hydroxyurea
Ifosfamide
L-Asparaginase
Leuprolide
Mercaptopurine (6MP)
Mesna
Methotrexate
Mitomycin C
Mitoxantrone
Nitrogen Mustard
Prednisone
Procarbazine
Tamoxifen
Thioguanine
Thiotepa
Vinblastine Sulfate
Vincristine Sulfate
VP-16 (Etoposide)

CANCER PREVENTION

13-cis Retinoic Acid (Retinol)
Calcium Carbonate
Calcium Carbonate + Fiber
Piroxicam
DFMO
Oltipraz
Phyllanthus amaus extract (woodchucks)
Folic acid
Beta-carotene
Retinol + Beta-carotene
Vitamin C + Vitamin E + Beta-carotene
Aspirin + Beta-carotene
13-cis Retinoic Acid + Beta-carotene
Isotretinoin + 4-HPR (in-vitro)
Beta-carotene + Canthaxanthin + DFMO
Retinyl Acid
4-HPR
Glycyrrhetinic Acid

BY-PASS BUDGET

Question. Dr. Broder, we have reviewed your NCI By-Pass Budget which requests $2,410,000,000 for FY 1991. This is $715,000,000 more than the President's Budget requested for NCI in FY 1991.

The By-Pass Budget requests almost $200,000,000 more for Cancer Causation and for Cancer Treatment than requested in the President's Budget. In addition, the By-Pass Budget requests 50 percent more than the President's Budget for Cancer Prevention and Control.

Please discuss NCI's high priority items as indicated in the FY 1991 By-Pass Budget and the effect of the President's Budget request on these priorities.

Answer. The research programs mentioned in your question -- Causation, Treatment and Cancer Prevention and Control will be streamlined under the President's Budget request, primarily in the area of research project grants, which cut across all research programs. Research grants in the FY 1991 By-Pass Budget are to be funded at full recommended levels for both competing and noncompeting approved grants, with approximately every one out of two competing grants being paid. Alternatively, the President's Budget funds one out of four competing grants and negotiates them down by 20 percent, i.e., grants would generally be reduced 20 percent below the recommended levels achieved during peer review. This will pose special challenges to NCI grantees. Noncompeting grants under the President's Budget will be downward negotiated 4.7 percent. Specifically, drug development (preclinical) research, and clinical trials will be reduced in scope, vaccine research will not be accelerated as rapidly under the Causation program, and some intervention research supported under the rubric of the Cancer Prevention and Control program will be delayed. Also, a great deal of cancer causation and cancer treatment activities are performed by cancer centers. In FY 1991, we expect either to reduce the number of cancer centers in our portfolio, or to require significant downward negotiations. The Committee should note that funds for a supercomputer ($34 million) displayed in the By-Pass under the Treatment and Tumor Biology programs have been appropriated in FY 1990 to the Office of the Director, NIH, to be transferred to NCI at a later time in FY 1990.

Other major program assumptions included in the FY 1991 By-Pass follow:

- Minority research efforts would be enhanced to determine differences in cancer etiology and survival for Blacks, Hispanics, Hawaiians and Native Americans, as well as expand the number of Historically Black Colleges and Universities involved in prevention awareness efforts and to attract minority students to pursue careers in the biomedical sciences;

- Over 65 research focus to determine survival/mortality differentials in the over age 65 populations compared with those under 65. Awards to be made alone, or through co-funding arrangements with the National Institute on Aging, in areas of expertise and opportunities relative to the prevention, early diagnosis and treatment of people over 65;

- Diagnosis research program to be increased to expedite the transfer of new diagnostic approaches into clinical application;

- Women's cancer detection program to expand and enhance efficacy of outreach activities relative to mammography and Pap tests; and

- Information dissemination activities to expand the Cancer Information Service (CIS) to fully support 26 regional offices and to provide each with health educators, as well as to augment patient education activities aimed at the elderly, minorities, rural populations, and other underserved Americans.

All of the programs listed above will be funded under the President's Budget request. NCI will always support its highest priorities, and the President's Budget will permit the traditional excellence of the NCI to continue. The speed with which specific research is accomplished and transferred to the public may be affected by the level of resources available.

VACCINE DEVELOPMENT

Question. Dr. Broder, I understand that an area of cancer research that you are pursuing is vaccine development: Vaccines particularly with regard to cancers caused by viruses and vaccines to prevent the recurrence of cancers. What are the prospects for the effective use of vaccines in the war against cancer?

Answer. The prospects for the effective use of vaccines in the treatment and prevention of cancer are good, within certain settings. However, the possibility of producing a cancer vaccine is complicated by the fact that cancer is a diverse set of diseases. Some cancers are known to be caused by specific etiological agents, such as viruses, while others are still of uncertain origin and appear to represent a multi-step disease process. Therefore, it is likely that separate conventional vaccines would have to be designed for each of the various forms of cancer and would have to address their unique etiologies and biological features.

The conventional vaccine approach depends on the ability to identify specific antigens associated with a particular disease entity or neoplasia and to elicit an appropriate protective host immune response to those antigens. Traditional infectious disease vaccines have elicited both humoral (blood) and cellular immune responses to the surface antigens of infectious agents. Thus, for those cancers in which viruses play a major role, a conventional vaccine approach could be feasible. Such a vaccine should be designed to prevent initial virus infection, and could additionally prevent the cancers associated later in life with that virus. An example of such a potentially successful approach is the use of the hepatitis B virus (HBV) vaccine to prevent chronic carriage of that virus and subsequent development of hepatocellular carcinoma (cancer of the liver).

Alternatively, a therapeutic vaccine approach could be used in which tumor antigens and/or modified cellular substances appearing during the neoplastic process are reintroduced into the patient to stimulate antitumor activity and prevent the spread or recurrence of the tumor. These vaccines could be considered for such diseases as cervical carcinoma, where tumor regression apparently associated with an immune response to papillomavirus antigens has been observed in some patients. The cell-mediated immune response appears to play a critical role in containing virus infection, especially in the case of latent viruses. This factor may be critical to the successful development of vaccines to tumor viruses. If the usual humoral immune response is not totally effective, and even a limited number of latently infected cells are established in the body, the appropriate cell-mediated response must be available to deal with these latently infected cells before they serve as a focus for new tumor formation.

For tumors of non-viral etiology, which presently probably represent the vast majority of human tumors, vaccine antigens must be both tumor specific and applicable to a large segment of the potentially at risk population for the vaccine concept to be workable. Recent work has demonstrated that it is possible to identify a subset of cells in the immune system of cancer patients that specifically recognize the patient's tumor and that when expanded in tissue culture and then reinfused into the patient, cause regression of the tumor. These cells (the so-called TILs or tumor infiltrating lymphocytes) represent the current evidence that the human immune system can specifically recognize and kill tumor cells and constitute the foundation for the NCI's future efforts to employ cellular immunotherapy in a clinical setting. While this approach differs from the conventional vaccination strategy for viral disease in that it employs specifically sensitized cells, it incorporates the same elements of destruction of a foreign entity based on specific recognition by the immune systems. In the future, it might be possible to identify certain special proteins that elicit TIL cells in a patient's body. Such special proteins could then be used to vaccinate a patient following surgery for a tumor.

In addition, the National Cancer Institute has recently awarded a grant for a Phase III trial of the vaccinia melanoma oncolysates (VMO) vaccine. The VMO vaccine, which is comprised of the smallpox vaccine virus and melanoma cell membranes, is designed to stimulate the body's own immune system and help it destroy any melanoma cells that have remained in the body after surgery.

SUPERCOMPUTER

Question. Last year the Committee included $34 million for the purchase of a supercomputer. While the Committee included the funding in the Office of the Director, the computer is to be used primarily by the Frederick Cancer Center. Where do we stand in the effort to procure this computer?

Answer. An Intra-agency Agreement between the Office of the Director, NIH and the National Cancer Institute (NCI) covering the handling of the $34 million will be finalized soon. This agreement transfers the money from OD, NIH to the NCI so that a contract can be awarded by September 30, 1990.

We have completed a very thorough Requirements Analysis which presents a description of the current supercomputer environment at our Advanced Scientific Computing Laboratory in Frederick and describes in great detail the target environment which we expect once the upgrade is completed. This document covers such topics as the expected improvements in research capabilities we hope to achieve and the system objectives and requirements necessary to realize those goals within the allotted budget. The Requirements Analysis has been incorporated into a Cost/Benefit Analysis which presents a description of alternative systems to meet the anticipated requirements and then compares the relative costs and associated benefits of each alternative. Both of these documents form the core of the Agency Procurement Request (APR) which has been prepared and forwarded to the General Services Administration in order that a Delegated Procurement Authorization (DPA) can be issued to the NCI to proceed with this acquisition.

We anticipate that an award will be made this fiscal year through the normal competitive process.

EVENTS IN EASTERN EUROPE

Question. Dr. Broder, do the unfolding events in eastern Europe present the increased potential for cooperative research efforts with those countries?

Answer. Yes, scientific collaborations, including scientist exchanges, continue to increase in number and scope. In addition to Eastern Europe, we are very optimistic that the changing situation in Latin America will allow for greater international scientific cooperation in the western hemisphere as well.

The Soviet coordinator for the U.S.-Soviet bilateral program has proposed many more, and longer-term, visits of Soviet cancer researchers to American laboratories. Soviet Ambassador Dubinin, in a meeting with me, noted that he was most supportive of these scientific collaborations and exchanges. Of particular note, discussions are underway exploring the feasibility of establishing two U.S.-Soviet cancer institutions, one in Moscow and one in the Soviet Far East. The NCI is prepared to assist the Soviets in the training of their future scientific faculty.

A U.S.-Hungarian workshop was held last fall in Budapest to evaluate the 10-year old bilateral collaboration between the U.S., Hungary, and Poland. Its continuation was endorsed, and the Polish and Hungarian coordinators for the program have enthusiastically responded to NCI's initiative of providing information databases to eastern European cancer institutions, using compact disc technology. We think this kind of outreach will provide significant dividends.

In the past, very few contacts were permissible between cancer researchers from East Germany, Czechoslovakia, or Yugoslavia, and their American counterparts. Because of the dramatic changes within these nations, the first scientific exchanges with NCI and other U.S. laboratories have now been scheduled for this spring.

Question. Additionally, what is the potential of extending assistance to those countries with regard to the preventive health care information you have developed for the various cancers?

Answer. The startling events in eastern Europe (coupled with important events in Latin America, e.g., Argentina, Chile and now Nicaragua) are increasing the potential for exciting interactions involving U.S. scientists and scientists in other countries. NCI is presently being flooded with requests from foreign graduate and medical students, recent doctoral degree recipients and established scientists for research experiences in the United States. In an attempt to enhance basic science, prevention and treatment throughout the world, NCI continues to expand programs aimed at dissemination of information for professionals by: 1) providing more journal subscriptions to foreign cancer research institutes and to medical schools; 2) setting up additional demonstration projects in information dissemination based on compact disk technology; and 3) encouraging additional bilateral or multilateral workshops and related scientific exchanges. Training scientists, physicians, and other health care professionals is a high priority.

Preventive measures such as aiding in the development of national cancer control plans, promoting professional education, anti-smoking campaigns, dietary and other interventions aimed at reducing cancer incidence will be supported. Accomplishments in the area of early detection, to reduce cancer mortality, will be transferred to other countries as well.

The international activities supported by the NCI are important for scientific and humanitarian reasons. Moreover, perhaps in some small way, the activities of the NCI can serve as a positive force to stabilize the positive momentum of change now underway in several parts of the world.

OBSTACLES TO CLINICAL TRIAL ENROLLMENT

Question. Dr. Broder, in your report to the Committee entitled "Ways to Enhance the Widespread Application of Treatment Advances," you addressed several obstacles to accrual to clinical trials nationwide. One major problem is that private third party payers are reluctant to provide reimbursement for the non-research costs of cancer clinical trials. Such policies provide barriers to clinical trial enrollment and deny deserving patients access to state-of-the-art treatment. Please give us your thoughts on alternatives to private third party payment and other options for reconciling this problem.

Answer. Third party payers, including the Health Care Financing Administration (HCFA), Blue Cross/Blue Shield, and other private insurers have become increasingly reluctant over the past several years to reimburse hospitals and patients for the costs of the non-research, routine medical care that is administered in the setting of cancer clinical trials. While NCI-sponsored clinical trials may involve experimental therapy in the technical sense, they are really providing state-of-the-art treatment. Already these policies are slowing accrual to some NCI-sponsored Phase I and II studies and, if continued, they could significantly decrease the pace of clinical progress in our country. I would like to suggest some alternatives for resolving this important problem:

1. The Medicare statute authorizes the Health Care Financing Administration (HCFA) to provide payment for medical treatments which are "reasonable and necessary." It has been HCFA policy to interpret "reasonable and necessary" to mean "safe and effective" and non-investigational. According to HCFA policy statements, "Medicare will not pay for an investigational drug or the physician charge for administering the drug because we believe that experimental drugs used in clinical trials are not reasonable and necessary, since their safety and efficacy have not been established. However, if admission to a hospital is reasonable and necessary, payment is made, unless the sole purpose of admission is to receive a noncovered item or service."

NCI believes that, for cancer patients for whom no significant, effective therapy exists, NCI-sponsored clinical trials represent the best available therapy. For some patients, such trials provide the only chance for effective treatment. NCI believes, therefore. that NCI-sponsored clinical trials constitute "reasonable and necessary" treatment for cancer patients. NCI clinical trials undergo rigorous peer review and monitoring. HCFA is currently in the final stages of developing their Medicare coverage guidelines as stated in the January 30, 1989 Federal Register. One alternative for solving the reimbursement problem for Medicare recipients is for HCFA to expand the definition of "reasonable and necessary" to include NCI-sponsored, scientifically-sound cancer clinical trials. NCI takes its responsibilities to ensure that its cancer trials represent state-of-the-art therapy very seriously, indeed. Such an action by HCFA may independently influence the policy-making of Blue Cross/Blue Shield and other private insurers since federal standards are often more widely adapted. If not, however, state regulators could then require such conforming changes by all other third party payers.

2. Educating consumers (patients) about the importance and benefits of clinical trials and informing them about which insurance companies provide the best coverage for investigational cancer therapies are two ways to change private insurance policies through consumer involvement. Private insurers can underwrite potential additional costs associated with NCI-sponsored investigational therapies either through "reinsurance" programs such as that instituted by Blue Cross to cover some bone marrow transplantation, by offering consumers specific insurance riders which can be purchased as an adjunct to existing coverage, or by increasing policy holders' insurance premiums generally. No published data currently exist comparing the costs of patients on clinical trials versus the costs of patients treated with standard care. The National Center for Health Services Research (NCHSR) has recently conducted a study comparing the costs of hospitalized cancer patients who are treated with investigational therapy to those treated with standard therapy. The results of this study are expected to be published in the Spring of 1990. Nevertheless, the magnitude of any potential increase would not necessarily be large.

NCI has undertaken several programs to educate patients and the general public about the importance and benefits of participating in clinical trials. Practicing community oncologists are working to educate citizens about various insurers and their policies regarding coverage of investigational and off-label cancer therapies. Our network of community clinical oncology program units is very important in this regard. In the long run, efforts to involve the consumer in the negotiations with private insurers will be an important part of solving this problem.

3. The formation of a national committee to guide decision-making about reimbursement for investigational therapies has been a focus of discussion at the ongoing proceedings of the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS (the Lasagna Committee). This committee is chaired by Dr. Louis Lasagna and was constituted by the President's Cancer Panel at the request of then Vice President George Bush. Such a national committee may make recommendations regarding which investigational therapies for which diseases are worthy of third-party reimbursement and might seek to bring a national consensus to such decisions. Private third-party payers

as well as HCFA may be willing to follow such guidelines because only those therapies with sound scientific rationale would be recommended for coverage. Insurers would then be in a better position to distinguish and deny coverage for unproven therapies which lack a scientific basis. The Lasagna Committee's report to the President's Cancer Panel with their final recommendations is expected in the Spring of 1990.

4. NCI believes that, because NCI-sponsored clinical trials represent the best therapy available to cancer patients, it is reasonable for third-party payers to reimburse the non-research medical costs. However, should private and federal insurers continue to deny such coverage, alternative funding for the patient care costs of clinical trials will be needed in order to support clinical research and the vital role it plays in the biomedical research enterprise. Who else might pay for the non-research costs of clinical trials? The alternatives are 1) the patients; however, restricting access to clinical trials to patients who can pay the treatment costs would create major inequities in access to investigational therapies and de facto would work against the interests of people who are poor or underserved, 2) the biotechnology and pharmaceutical industries, and 3) the federal government. For the latter two alternatives, any move to shift the costs to research sponsors (industry, academia or NIH) would severely hamper clinical research, and absent a significant infusion of new monies. The support of clinical research will ultimately be passed on to the citizen or consumer in ways that could be inequitable. Though these cost sharing alternatives could be explored, any solution other than having the patient care costs of clinical research paid through existing third-party reimbursement mechanisms will require careful coordination and planning to avoid significant disruptions in clinical research.

5. Some leaders in the biomedical research community have suggested that broad policy discussions are needed to better formulate new policies for funding clinical research. Such discussions would involve all segments of the biomedical research community, especially consumers. What is the best way to pay the patient care costs of clinical trials? Should clinical research and the development of better therapies be supported through tax dollars, higher insurance premiums, higher prices for consumer goods (because companies' cost of doing business through insurance premiums have increased) or through higher costs of marketed drugs? What are the most equitable and efficient ways of supporting exciting clinical research to embrace all segments of society, including the poor and powerless?

The Institute of Medicine's (IOM) 1988 study, "Resources for Clinical Investigation," considered this issue of reimbursement for clinical research and recommended that "Third party payers (government and non-government) should pay the necessary and appropriate patient care costs for beneficiaries enrolled in approved clinical investigation protocols." Third party payers have not changed their policies or practices to conform with IOM's recommendations and additional policy discussions will be warranted to address the future of clinical research.

GUIDELINES FOR FUTURE CANCER CENTERS

Question. Recommendations from the recent Institute of Medicine's study entitled "Report on a Stronger Cancer Centers Program", indicated the need for NCI to develop guidelines for the future expanded role of cancer centers. What plans is NCI making to accelerate the pace of cancer research and to transfer new therapies from research into widespread clinical practice?

Answer. Since the passage of the National Cancer Act in 1971, NCI has developed an extensive national network for dissemination of treatment information. Components of this network carry out both the process of reaching consensus on recommendations for the treatment of various forms of cancer and information dissemination to physicians and cancer patients. The major components of this network follow.

- The Physician Data Query (PDQ) system, an on-line computer network contains NCI's official recommendations on "state-of-the-art" standard therapies. The PDQ Editorial Board develops consensus recommendations for the therapy for every major type of cancer. PDQ also lists investigational protocols being carried out in the U.S. and Europe that test new therapies in the treatment of cancer.

- A network of Cancer Centers conducts extensive laboratory and clinical evaluation of new cancer therapies as well as coordinating cancer prevention, screening, and educational programs in their communities. Cancer centers serve to move basic research findings quickly into developmental and applied research. Many ideas generated in cancer centers become suitable for widespread clinical trial testing. The two-way communication between the cancer centers and other NCI programs will result in even greater participation of centers in nationally coordinated trials for prevention, diagnosis, and therapy. In addition, the new centers guidelines for comprehensiveness emphasize training and information services to benefit health care professionals.

- The Cooperative Groups are multi-institutional organizations which conduct clinical trials of new cancer treatments. More than 25,000 patients are entered onto therapeutic clinical trials through the Cooperative Groups every year.

- The Community Clinical Oncology Program (CCOP) consists of community-based clinics and hospitals which enable practicing physicians to participate in clinical trials in cancer treatment, prevention, and education. This network can be significantly useful in reaching rural Americans and other underserved populations.

- The Clinical Cooperative Group Outreach Program (CGOP) is another mechanism that allows community physicians to participate in Clinical Cooperative Group trials. Five of the 11 Clinical Cooperative Groups conduct such outreach efforts which serve to make promising new therapies more accessible to cancer patients who may not live in or near a large metropolitan center.

- The Cancer Information System (CIS), a national toll-free telephone service (1-800-4-CANCER), provides immediate answers to cancer-related questions from patients, their families, health professionals, and the general public. We handle nearly 500,000 calls per year on this system.

- Clinical Updates are periodic mailings sent by the NCI to practicing physicians to alert them to important new advances in the treatment of common malignancies. The NCI has relied upon this mechanism twice: once in May, 1988 to alert physicians to new data demonstrating a significant benefit of adjuvant therapy for women with "node-negative" breast cancer, and again in October, 1989 to update physicians on the impact of adjuvant therapy in patients with Dukes' C colon cancer. The response to both of these mailings was very significant.

- The NCI periodically sponsors Consensus Development Conferences in which all of the relevant laboratory and clinical evidence regarding the treatment of a specific cancer is critically reviewed and specific recommendations regarding the treatment of that cancer are issued. Such consensus conferences are held whenever emerging evidence suggests that a significant change in the approach to a particular cancer may be warranted. Consensus conferences are planned for breast and colon cancers in the upcoming year.

Question. Are special considerations being given to disseminate these therapies to physicians and hospitals in underserved and rural areas?

Answer. An important new element has been added to the essential characteristics required of comprehensive cancer centers, that is, community service and outreach. Comprehensive cancer centers will be required to define the communities they serve and maintain productive outreach efforts in that community. Comprehensive cancer centers are expected to conduct programs in cancer prevention and control that meet the needs of underserved populations (e.g., minorities, people over 65, rural populations). In those areas where there are no existing cancer centers, especially in rural, low population density areas, efforts will be made to network surrounding cancer centers with each other and with community oncology groups in order to increase and improve outreach efforts to these areas. In addition, the NCI is planning an initiative to encourage the establishment of new cancer centers in underserved geographical areas of the Nation in order to reach more people in underserved and rural areas.

The Cooperative Group Outreach Program (CGOP) and the Community Clinical Oncology Program (CCOP) provide funds to involve community physicians and their patients in NCI-approved clinical trials. This has been shown to be a very effective mechanism for the dissemination of state-of-the-art cancer care to patients in underserved and rural areas. More than 700 hospitals across the country participate in these programs. A new initiative, the Minority-Based CCOP will extend the benefits of participation in clinical research to minority patients by providing funds for clinical trials to institutions that serve a large minority population. We are also increasing the reach of our cancer information services to reach rural populations by adding new monies for this purpose.

Additionally, a research initiative planned for FY 1991 will explore innovative approaches to strengthen the application of state-of-the-art cancer diagnosis and management practices in rural areas by enhancing links between rural health care providers and regional cancer specialists.

AIDS ACCOMPLISHMENTS

Question. Doctor, tell us what you list as your institute's major accomplishments in AIDS during the past year?

Answer. Although not the lead NIH agency for AIDS research, NCI has an important role in AIDS drug and vaccine development, investigations of the pathogenesis of AIDS, the biologic mechanisms by which the HIV causes infection, immune system destruction, and the study of HIV-related cancers. It is worth noting the NCI intramural program has become one of the most important centers in the world for the development of therapeutics used in the treatment of children with AIDS.

AIDS Drug Screen/Preclinical Drug Development

The AIDS Drug Screen was initially established in 1987 to screen compounds for HIV activity and over the past year, the capacity of this screen has increased from 300 to 900 assays per week. As a result of this screening effort, 28 unique structures/classes of drugs with anti-HIV activity have been identified and are undergoing further testing.

Additionally, various products from outside contributors worldwide in academia or in the pharmaceutical industry are tested in the AIDS Drug Screen. Recently, a promising and unique class of compounds derived from a natural product, cyanobacteria, have been identified and are under development. At present, there are three very promising lead compounds which are undergoing further preclinical evaluation and Phase I testing should begin on the most promising of these within a year.

Over the past year, NCI scientists have completed the Phase I trial of dideoxyinosine (ddI). The results are very promising and show the compound to produce significant improvements in a variety clinical parameters in AIDS patients. Because of these encouraging results, ddI has entered Phase II testing through the National Institute of Allergy and Infectious Diseases/AIDS Clinical Trials Group (NIAID/ACTG) network and has also been made available to the public through Treatment IND and compassionate release mechanisms. There is much that we still do not know about this drug, including the best way to avoid certain nerve damage and inflammatory damage to the pancreas gland. But we are at an advanced stage of testing this drug.

Additionally, studies on dideoxycytidine (ddC) alternating with AZT have matured over the past year and show this to be a well-tolerated combination therapy which has produced improvements in the laboratory markers of HIV infection. This year NCI is completing a Phase I study on recombinant soluble CD4 and has started a Phase I study on a variant of this molecule with a prolonged half-life in patients, IgG-CD4.

Nearly 2,000 children in the United States have AIDS. NCI scientists have studied several routes of administration of AZT in pediatric AIDS patients and have shown that AZT produces significant improvements in brain dysfunction with patients recovering their ability to reach developmental milestones. This and other studies have led to the New Drug Application approval in 1989 of AZT for pediatrics patients. NCI is also conducting a Phase I evaluation of ddI in children with symptomatic HIV infection and preliminary results also appear promising.

The development of effective therapies for HIV infection has lowered the incidence of new AIDS cases diagnosed in those HIV-infected populations with access to good medical care. Favorable changes appeared in the incidence of AIDS among homosexual and bisexual men beginning in mid-1987, shortly after AZT was released for persons with severe immunodeficiency and for persons with full blown AIDS. These changes can be accounted for largely, if not entirely, by the amount of AZT and other treatments in use demonstrating that effective medical therapies can decrease the incidence of AIDS.

Taking a new approach and utilizing bioengineering techniques, NCI scientists have developed a recombinant protein that combines a portion of the CD4 molecule with a powerful bacterial toxin, Pseudomonas exotoxin (PE). NCI has shown that this protein, CD4-PE, can attach to and kill HIV-infected cells in culture, suggesting that this compound may be a powerful weapon against AIDS infection in patients. Preclinical testing is nearly complete; current efforts are focused on producing quantities of CD4-PE that will enable its Phase I testing in humans. This work is being done in collaboration with Upjohn Company through a Cooperative Research and Development Agreement (CRADA).

A major breakthrough in AIDS research came this year when NCI scientists at the Frederick Cancer Research Facility, using the NCI supercomputer, were able to solve the puzzle of the three-dimensional crystallographic structure of the HIV-1 protease enzyme. The calculations for this project would have required over 30 days of time on a VAX computer but were accomplished in only 48 hours on the supercomputer.

The HIV-1 protease is essential for the replication of infectious virus and is, therefore, an attractive target for the specific design of inhibitors as potential antiviral therapeutics. With this structural analysis in hand, it is possible to custom design an inhibitor capable of halting the replication of the HIV. Subsequently, a specific inhibitor has been co-crystallized with chemically synthesized HIV-1 protease. The structural analysis has provided a clear picture of the interactions between the inhibitor and the protease. The detailed information gained from knowing folding patterns of the viral protease and those parts of the protease that specifically interact with the inhibitor, constitute the first described enzyme-inhibitor structure.

The binding of the HIV-1 gp120 envelope protein to the CD4 receptor on the surface of T-lymphocytes is the first event in

HIV-1 infection. A promising family of drugs acts against HIV-1 by inhibiting the virus from binding to the CD4 lymphocyte receptor. In order to screen and quantitate the effects of drugs on the gp120 envelope-CD4 receptor interaction, NCI scientists at FCRF have developed a simple and quantitative bioassay which measures the fusion between two cell lines, one of which expresses high levels of the HIV-1 envelope glycoproteins but no infectious virus, and the other expresses the CD4 receptor. Upon co-cultivation of the two cell lines, fusion takes place within 12 hours and the efficiency of fusion can be quantified. This assay system has been shown to be very sensitive in detecting inhibition of fusion by two anti-HIV agents, soluble CD4 and dextran sulfate. This mechanistic assay is potentially very powerful because it can be used to identify new drugs which inhibit HIV infection specifically by interfering with an infected cell's ability to fuse and transmit infection to a normal cell nearby.

Immunology and Pathogenesis

NCI scientists are evaluating the regulation of cellular activators (cytokines) in HIV-infected human monocytes and the role these cytokines play in the production of HIV by infected monocytes. It has been found that the induction of the cytokines IL-1, IL-6, IL-8 and TNF is decreased in HIV-infected monocytes, an event which may contribute to the immunosuppression associated with AIDS. NCI scientists have purified several nuclear proteins which bind to the regulatory regions of the HIV genome and have found that cyclosporin A inhibits the activation of these regulatory proteins. This is an important finding because understanding the regulation of HIV gene expression and finding compounds which modulate this regulation will be critical in controlling HIV infection. NCI researchers are also studying the application of cytokines to the treatment of AIDS. Growth factors and CSFs that can accelerate the replenishment of CD4 cells depleted by HIV infection are actively being sought. Over the past year, scientists have developed an in vitro assay for measuring the growth effects of various cytokines on precursor T cells from mice and rats.

NCI scientists have shown that there is a sequential loss of T helper cell immune function in asymptomatic, HIV-infected individuals that is predictive for progression towards AIDS and can be detected up to two years before any other signs of AIDS are observed. This early immune dysfunction may be due to the production of a type of "autoantibody" that blocks the interaction of the helper T-cells with other cells of the immune system (called antigen presenting cells-APC) that are required for their activation. This "autoantibody" is probably an antibody to gp40 of HIV that cross-reacts with all human lymphocytes that express class II histocompatibility antigens. Very recent preliminary findings suggest that a cell with suppressive or inhibitory potential can be detected in asymptomatic HIV-infected patients; efforts to isolate and characterize this factor have intensified. These studies are critical to our understanding of the mechanism responsible for the immunosuppression associated with AIDS, and should be useful in developing appropriate intervention strategies for HIV-infected individuals.

NCI scientists have, for the first time, identified a portion of the AIDS virus that is capable of eliciting a cytotoxic T-cell response. This cytotoxic T-cell protein and three other HIV-derived proteins recognized by helper T cells were tested in humans and found to react with antibodies found in some normal individuals immunized with a recombinant vaccinia virus containing the HIV envelope gene, as well as in asymptomatic HIV-infected individuals. T-cell immunity plays a critical role in the defense against the AIDS virus, both in the generation of antibodies and in the development of a cell mediated cytotoxic T-cell response. These peptides are likely to be important components in the development of an effective AIDS vaccine.

Work toward more effective diagnostic procedures continues. A very sensitive laboratory technique has aided the early detection of HIV infection. The polymerase chain reaction (PCR) technique detected HIV provirus in lymphocytes as much as six to 12 months prior to the first positive Western blot. Another study found the transmission of HIV infection to long-term sexual partners to be correlated with the severity of HIV disease (including the presence of p24 antigen or a low CD4 cell count) in the HIV-infected partner. Presence of genital herpes or gonorrhea in the uninfected sexual partner and lack of condom use in the preceding year also increased the likelihood of transmission.

Some patients are dually infected with human T-lymphotropic virus type 1 (HTLV-1) and human immunodeficiency virus type 1 (HIV-1). Noninfectious HTLV-1 virus induces the _in vitro_ production of large quantities of HIV-1 from peripheral blood leukocytes infected with HIV-1. This suggests the possibility that HTLV-1 may act as a cofactor for the development of AIDS.

Spindle-like cells have been successfully cultured for long periods of time from Kaposi's sarcoma (KS) tissue specimens taken from the lung, oral cavity, skin, orbit of the eye, tonsil, and pleural effusions of AIDS patients with disseminated KS. This study suggests that these cultured cells are abnormal smooth muscle cells of vascular origin. These cells have been cultured with the help of a novel growth factor obtained from a CD4-positive transformed cell line produced by the infection of human umbilical cord blood leukocytes by human T-lymphotropic virus (HTLV-II). Purification of this exciting growth factor is in progress.

AIDS Vaccine Development

Some of the target sites on the HIV envelope protein that have been most effective in eliciting an immune response appear to be located in a hypervariable region of the envelope protein, that region of the protein that varies with each strain of the virus and is most susceptible to mutation. Current investigations are underway to identify suitable peptides in a stable region of the viral protein so that a vaccine incorporating these peptides would provide protection against multiple strains of the HIV virus.

Working towards therapies aimed at bolstering the immune system as well as toward producing a vaccine, NCI scientists at the FCRF have been developing technologies to generate intact, noninfectious retroviral particles. Since intact virus is likely to be far more effective at generating an immune response than a single part of the virus envelope, scientists have been working on trying to make intact virus noninfectious so it can be used as a human vaccine. Recently, scientists have succeeded in making mutant HIV-1 particles which contain normal, mature gag proteins, reverse transcriptase, and are structurally normal. However, they do not contain viral RNA, and are therefore noninfectious and cannot replicate. Detailed studies are ongoing to substantiate that these mutant viral particles are noninfectious and to study the immune response that they generate in animals.

AIDS CONSTRUCTION NEEDS

Question. What are your construction needs in AIDS research?

Answer. The National Cancer Institute currently has $9.4 million in AIDS construction requirements. These funds are needed for refurbishment and expansion to provide approximately 22,000 net square feet of space in Building 470 at the Frederick Cancer Research Facility. Activities proposed for consolidation and expansion in this structure include those related to retrovirology as well as viral epidemiology, encompassing AIDS and associated cancer activities.

CLINICAL TRIALS

Question. Are there clinical trials or projects related to new treatments that you cannot do under the President's Budget?

Answer. Yes, while the President's Budget does provide funding for several new clinical trial efforts, there are high-priority projects which will remain unfunded. The following unfunded cancer-related trials would require about $100 million for the first year of funding; the AIDS-related trials would require about $14.7 million:

CANCER TREATMENT, DETECTION, or DIAGNOSIS TRIALS:

Trans-Retinoic Acid and Other Biologicals in Children with Leukemia and Selected Solid Tumors
Early Empirical Antifungal Therapy in Febrile Neutropenic Patients
GM-CSF for the Management of Patients with Fever and Neutropenia
Purigenic Receptor Agonist in Prostate Cancer
Attainment of Optimal Patient Accrual Rates in Contract-Supported Clinical Trials
Clinical Trials of Novel Therapeutic Agents (oligo-deoxynucleotides and immuno-toxin conjugates)
Trial of Anti-Growth Factor Therapy in Multiple Myeloma, Malignant Melanoma, Ovary and Prostate, Including Use of Suramin and Suramin Analogs
Increased Accrual of Minority and Other Underserved Populations in Clinical Trials
Increased Accrual into High-Priority National Clinical Trials, Including Patients Over Age 65
Expansion of Adoptive Immunotherapy/Combination Cytokine Trials/Gene Transfer Studies
Evaluation of the Role of Suppressor Oncogenes on Lung,

Colon and Breast Cancers
Trial of Photodynamic Therapy in Refractory Malignancies (including ovarian/bladder cancers and mesothelioma)
Expansion and Follow-up of Adjuvant Therapy Trials in Breast, Colon, and Rectal Cancers
Expanded Correlation in Clinical Trials with Laboratory/Basic Science Studies
Bone Marrow Transplantation Initiatives
Development of Diagnostic Imaging to Study Perfusion
Digitalization of Chest Radiography
Radiolabelled MoAb Studies
Synthesis of Compounds for Boron Neutron Capture Therapy
Imaging of Bone Marrow Tumors
Clinical PET Studies of Brain Tumor Metabolism
Use of Fludarabine for Treatment of Low-Grade Lymphomas
Clinical Application of Monoclonal Antibodies in Diagnositic Studies (Expansion)

CANCER PREVENTION & CONTROL TRIALS:

Funding of Three Additional Minority-Based CCOPS, Increasing Minority Patient Accrual
Prevention Clinical Trial within CCOPS/Groups Network
Finland Prevention Study - Collection of Additional Serum Samples for Follow-up Study
Fund Additional CCOPS to optimize patient accrual
Women's Nutrition Health Trial

CORE SUPPORT FOR CLINICAL CANCER RESEARCH:

Increased Support for Clinical/Comprehensive Cancer Centers to Support the Infrastructure of These Unfunded Clinical Trials

AIDS TRIALS:

Adoptive Immunotherapy in Children with AIDS (Expansion)
B1 Antibody for Treatment of B-Cell Lymphoma Associated With AIDS (Expansion)
Clinical Trials of Novel Therapeutic Agents (immunoconjugates, oligonucleotides, nucleoside analogs)
Trial of Anti-Growth Factor Therapy
Trial of Photodynamic Therapy in Kaposi's Sarcoma
Development of Diagnostic Imaging Strategies in AIDS
Digitalization of Chest Radiography
Treatment of High-Grade Lymphomas and AIDS

BY-PASS BUDGET

Question. Each year the NCI submits a By-Pass Budget. This budget reflects what I would call a true "needs" budget. Can you tell us what your request was for 1991 and how it compares with the President's submittal?

Answer. The 1991 By-Pass Budget totals $2,410,000,000 in contrast to that of the Administration's request of $1,694,059,000. A comparison is as follows:

- The By-Pass would fund 50 percent of approved new and competing research project grants paid at full recommended levels; the President's Budget supports 27 percent of new and competing grants paid at approximately 20 percent less than recommended levels.

- The By-Pass would pay continuing cancer centers at committed levels and competing centers at recommended levels; the President's Budget supports competing centers at least 15 percent less than recommended levels.

- The By-Pass would fully fund approximately five new centers; the President's Budget may require a reduction in the number of centers funded and/or extensive downward negotiations of the amounts provided to new and competing centers.

- The By-Pass would expand efforts to increase patient accrual to clinical trials through the Cooperative Group mechanism; increase the enrollment of minority and over age 65 populations in clinical trials; and significantly augment the prevention clinical trials network and patient accrual through an expansion of the Community Clinical Oncology Program mechanism; under the President's Budget, ongoing support for patient accrual to clinical trials will continue at last year's level of support.

- The By-Pass would support 50 percent of approved training applications, for approximately 1,600 trainees; the President's Budget maintains the same number of full-time training positions (FTTPs) as last year.

- The By-Pass includes $60,000,000 for the modernization and upgrading of extramural facilities as well as an expansion of the Frederick Cancer Research Facility; the President's Budget provides $1,479,000 for renovation and improvement activities at the Frederick Cancer Research Facility.

- The By-Pass would provide $388,000,000 and $94,000,000 for Intramural Research and Research Management and Support activities, respectively. These funds would expand efforts in the myriad of research areas supported by NCI, as well as provide full support for NCI's information dissemination activities supported under Research Management and Support. The President's Budget for Intramural Research and Research Management and Support provides $333,000,000 and $76,000,000 respectively and covers only mandatory requirements for both areas.

Question. Can you tell us what were the major areas of emphasis within your By-Pass Request?

Answer. There are a number of major areas of emphasis within the 1991 By-Pass Budget. These include:

- Minority and Underserved Population Initiatives: increase efforts to determine any differences in cancer etiology for minority populations; expand the number of historically Black colleges and universities involved in cancer prevention awareness efforts; increase support for the NIH Minority Access to Research Careers (MARC) program to attract underserved young people to pursue careers in the biomedical sciences; increase cancer prevention and early detection initiatives in Hispanics; increase cancer control initiatives in Native Americans (including Native Hawaiians); and improve cancer information and technology transfer to rural Americans.

- Over 65 Focus: expand efforts to determine survival/mortality differentials in the over 65 populations when compared with those under 65; and to provide supplements, by NCI or through co-funding with the National Institute on Aging, in areas of expertise and opportunities relative to cancer prevention, early diagnosis and treatment for people over 65.

- Diagnosis Program: increase efforts to expedite the transfer of new diagnostic approaches into clinical application.

- Drug Development Activities: expand natural products chemistry research and screening efforts in preclinical drug development for new anti-cancer therapeucics.

- Vaccine Research: provide a new emphasis on cancer-related vaccine research, viral research, specific antigens, and markers for tumors, including tumor infiltrating lymphocytes (TIL) therapy and the special cell surface markers that elicit such host defense cells.

- Women's Cancer Detection Program: expand outreach activities to promote the use of mammography and Pap tests as effective screening measures.

- Information Dissemination: expand the Cancer Information Service (CIS) to fully support 26 regional offices and provide each with health educators; to increase emphasis on projects for the elderly within patient education activities; to develop more public service announcements, especially outreach activities that target minorities and other underserved Americans; and to increase efforts to develop effective methods for information dissemination in cancer prevention, diagnosis, and treatment for those segments of the population who are poor or educationally disadvantaged.

Other By-Pass initiatives include an expansion of smoking prevention/cessation efforts funded out of the cancer prevention and control mechanism and additional support to the Nutrition Laboratory and other chemoprevention and nutrition-related activities.

CANCER STATISTICS

Question. The press recently reported that major discrepancies in "cancer death rates still loom higher for Blacks than whites." You discussed this topic with us in considerable detail last year. Can you update us on what has transpired this year?

Answer. NCI is very concerned about the disparity in mortality rates between Black and white Americans. Black Americans are known to experience disproportionately high mortality rates for cancer. Available data for the years 1983 to 1987 indicate that for all cancer sites combined, Blacks have a 10 percent greater risk of developing cancer and a five-year survival rate that is 27 percent lower than that for whites. Both higher incidence rates coupled with poorer survival have led to an overall mortality rate that is about 30 percent higher for Blacks than for whites: about 40 percent higher for Black males and about 20 percent higher for Black females.

There are a number of cancers for which Black Americans experience drastically less favorable outcomes when compared to that of their white counterparts. Esophageal cancer has the poorest Black/white mortality ratio among the major cancer sites, with Blacks experiencing a mortality ratio that is three times higher than that for whites. The mortality rate for prostate cancer is more than twice as high among Blacks while mortality from cancer of the cervix uteri is two and one-half times higher for Blacks than for whites. It is striking to note that the mortality rate among Black females for cancer of the corpus uteri is 70 percent greater than for white females despite the fact that the incidence rate for this cancer in Blacks is 40 percent lower. This disparity is reflected in a survival rate that is only 65 percent of that for white women. In a similar fashion, the mortality rate from cancer of the urinary bladder should be much lower for Blacks than for whites based on a lower incidence rate. Nevertheless, the poorer survival experienced by Blacks results in a mortality rate that is essentially the same for both races.

NCI recognizes the critical need to give special attention to the cancer burden borne by Black Americans. In response to this important issue, the National Cancer Advisory Board initiated the National Black Leadership Initiative on Cancer (NBLIC) which involves the participation of individuals who are committed to achieving a high level of cancer prevention awareness among Black Americans. Because cancer is to a great extent preventable, the prevention and control of cancer in minorities can be achieved through the adoption of such changes in lifestyle as the avoidance of tobacco products, the adoption of high fiber-low fat diets, an increased involvement in screening and early detection activities, and gaining access to state-of-the-art care and treatment.

As a first step in mobilizing a significant part of the minority community in this effort, NCI recruited a regional coordinator for each of the six cities that served as locations for the NBLIC regional meetings. These meetings, which took place over the course of the past year in Atlanta, Los Angeles, Chicago, New York, Washington and Houston, brought together Black leaders from many fields -- academia, clergy, medicine, business, public health, the media, state and local legislatures -- in order to develop strategies for initiating or enhancing cancer control and prevention activities in the Black communities of their respective regions. The regional coordinators represent an NCI presence in the community. Regional coordinators serve a liaison role in identifying community resources, facilitating their most effective utilization, assisting communities in obtaining and optimizing support from NCI in implementing local cancer prevention and intervention programs.

The second part of this community-based NCI plan is to establish grant-supported inner-city demonstration centers. An essential criterion for these awards is for the grantee institution to have demonstrated the ability to work in collaboration with the minority community in programs of education and health promotion. NCI believes that reduction in mortality among minority populations at high risk for specific cancers can be achieved by improving their access to therapeutic interventions of proven effectiveness. An increase in screening and early detection programs that are conducted in high density minority population areas should further serve to identify cancers at an earlier stage when they can be more successfully treated. A Request For Applications in support of this initiative will be issued in FY 1990.

Other NCI efforts to address the special needs of Black Americans include the development of "Special Populations" programs that are directed toward the Black community. NCI is currently conducting trials on smoking prevention and cessation that target Black Americans. NCI will continue to work with a network of Black leaders to disseminate the most effective smoking prevention and cessation strategies as the results of these ongoing trials become available.

NCI plans to initiate through the Community Clinical Oncology Program (CCOP), a special effort to serve predominantly minority communities. The minority CCOP program will enhance current NCI efforts designed to close the gap in survival between white and Black cancer patients enabling academic and community oncologists with large minority populations to gain enhanced access to state-of-the-art cancer management by participating in treatment and cancer control clinical trials.

NCI will continue ongoing efforts designed to determine how to increase the use of Pap smears by low income and Black women and to provide follow-up medical treatment for women diagnosed with early stage cervical cancer. NCI also plans to continue and expand a number of programs designed to enhance the capacity of state and local public health departments to make screening programs for breast and cervical cancer more readily available to low income women.

Finally, a proposal to expand the Surveillance, Epidemiology and End Results Program (SEER) in order to provide more adequate statistical coverage of minority populations is currently undergoing review.

Question. What about the District of Columbia?

Answer. With respect to the District of Columbia, NCI has taken a number of steps to address the problem of increased cancer mortality rates found in the Nation's capital. Promotional efforts that target smoking prevention and cessation, low-fat high-fiber diets, moderate alcohol use, and compliance with cancer screening guidelines are currently underway. Strategies include public service announcements on Black-oriented radio and TV stations, health oriented messages printed on Metro subway posters and fare cards, and endorsements by local Black athletes. For example, Wes Unseld has helped us create a special stop-smoking public service T.V. announcement for D.C. youth.

In June 1989, NCI awarded the D.C. Department of Health and Human Services a seven-year data-based intervention research cooperative agreement. The purpose of the project is to develop, implement, and evaluate a program to reduce cancer incidence and mortality among Black Americans living in the District.

Project staff are currently analyzing D.C. cancer data ' identify those areas within the District and the various subpopulations who are at elevated risk for cancer development. Four technical advisory committees have been created to make recommendations in the following areas: prevention and cessation of tobacco and alcohol use, cervical and breast cancer detection and access to state-of-the-art treatment, dietary modification to lower fat intake and increase fiber, and the reduction of occupational exposures to potentially carcinogenic agents.

Each advisory committee will submit a report which will be integrated into an overall cancer prevention and control plan for review by the District of Columbia Cancer Consortium. It is anticipated that a final report will be made available by September 1990.

Efforts to implement the cancer plan and to test interventions designed to address designated priority areas will follow, along with educational activities to inform the city council and key government officials about specific cancer problems in their areas and their potential solutions.

NCI staff have contacted the D.C. Department of Health, Bureau of Cancer Control to explore ways in which to transfer NCI intervention expertise and resources to improve cancer screening efforts in the District. In-service training has been arranged for nurses, dentists, and other primary health care providers to screen for breast, cervix, colon, and head and neck cancers for which the District has particularly high mortality rates.

NCI has made arrangements through the D.C. Public School System to "adopt" McKinley high school, and will attempt to develop a similar relationship with Banneker, the academic high school in District of Columbia. The program will include science enrichment courses for students, books, equipment, prizes for science projects, and similar efforts to encourage minority students to pursue careers in the health sciences or biomedical research. A secondary goal of the Adopt-A-School Program is to provide important public health messages to participating students. Health prevention and educational messages have been incorporated into large group seminars held on a bi-monthly basis. Topics have included Acquired Immunodeficiency Syndrome (AIDS), the effects of tobacco use, and the biology of cancer and minority health issues. The importance of prevention, early detection and screening has been stressed and students are encouraged to discuss these topics with their parents.

NCI staff have contacted appropriate officials of institutions around the Washington, D.C. area to increase research opportunities for minority individuals. Special emphasis is being placed on the program announcement entitled: "Initiatives for Under-represented Minorities in Biomedical Research". Funds have been included in anticipation of increased awards under this NIH-wide program.

The NCI has explored the possibility of providing supplemental funds to NCI-supported research at the University of the District of Columbia, Howard University, and other institutions in the metropolitan area, for the purpose of enhancing cancer prevention and control efforts at those institutions and in the communities which they serve. Examples include:

- A Cancer Education Grant (R25) at Howard University for high school student and teacher training programs.

- Minority Access to Research Careers (MARC) grant at the University of the District of Columbia to involve students in summer research in NCI intramural laboratories.

- Basic research grants active at all area institutions to allow involvement of minority investigators in cancer research projects.

- Clinical Cooperative Group awards at local institutions to support increased accrual of minority patients and enhanced involvement of community physicians in NCI-sponsored clinical trials.

These initiatives all involve careful peer-review for excellence, and we feel a great deal of progress will be possible.

GRANT FUNDING

Question. From prior testimony of the NCI Director, we are aware that funding grants at the peer reviewed level may not always be possible. What do your advisory bodies have to say about this, specifically related to centers. Would they rather fully fund the centers or pay fewer at full recommended levels?

Answer. Mr. Chairman, I believe the question has to do with the current choice given available funds: reduce the number of centers receiving a core grant; or keep the number constant, but significantly downward negotiate the funds provided to each center. If this is the choice, most experts have advised us to avoid significant downward negotiations, recognizing that this means a loss of centers. I agree with this choice. We certainly do not want to lose centers. But downward negotiations below a certain point threatens the excellence of the individual centers and the total portfolio.

FUNDING FOR CONSTRUCTION

Question. For the past couple of years funds for extramural construction as well as the building maintenance at the Frederick Cancer Research Facility has not been included in the budget request. This year about $1.5 million is included. Is this adequate?

Answer. Concerning extramural construction requirements, currently the NCI has on hand approximately $11 million of peer-reviewed approved construction applications with an additional three pending peer-review in 1990. To date, NIH has provided $2 million from the 1990 appropriation for these requirements.

Regarding the Frederick Cancer Research Facility, the ages of the buildings range from one to 40 years, with the majority between 20 and 30 years. These buildings have outdated mechanical systems, such as heating/ventilation/air conditioning (HVAC), dating from the original construction. The requirement for these systems to operate continuously hampers our efforts to provide routine preventive maintenance programs which would prolong their useful lives. Stringent demands for high level containment for AIDS research and the age of the Facility itself will require the continuation of upgrade activities in 1991 and beyond. The $1.5 million included within the President's Budget will permit NCI to maintain those urgent maintenance activities. However, additional requirements exist to repair and modernize other structures. We are also actively considering establishing a day care facility. There currently is no suitable facility for this purpose. Such a facility is necessary for maximum efficiency of operations and for optimal career opportunities to employees with young children.

BIOMEDICAL RESEARCH FACILITIES

The Committee has recognized the need for upgrading and maintaining biomedical research facilities throughout the Nation. In that regard, $15 million was provided in 1990 at the NIH level. Was the NCI able to fund any construction projects with these funds?

Answer. To date, NCI has been allocated $2,000,000 in construction funds to award the two pending peer-reviewed grant applications with the best priority scores.

It is our understanding that NIH is issuing a request for applications in the amount of $2,800,000, and cancer construction grants are likely to be included in the final awards.

CANCER CENTERS

Question. Cancer centers continue to be very essential components of the total Cancer program. During 1989 you phased out about four centers. What is the status for 1990?

Answer. NCI has not yet finalized its FY 1990 funding plan for centers; however significant reductions to competing awards as well as downward adjustments to the noncompeting awards will be necessary to maintain the same approximate number of total centers in 1990, as suggested in the subcommittee report language from last year. Such mandatory downward adjustments pose special challenges for cancer centers.

Question. In last year's report language we stated that no additional centers be phased out. Given the final 1990 budget level, what are you doing with centers?

Answer. The Institute faced a similar situation in 1989 and, after discussion with advisory groups, decided that non-competing centers would be funded at committed levels and competing centers at approximately 85 percent of recommended levels. Any greater reduction to competing centers was felt to be a serious depreciation of the value of peer-review recommendations. As you know, this decision required that four centers be phased out in 1989.

NCI is currently exploring ways to ensure that scientific excellence continues within the Cancer Center program while negotiating a reasonable reduction from the peer-reviewed recommended funding levels for competing centers or our commitment levels for noncompeting centers. Our goal is to maintain the stability and availability of resources for all centers, including newly proposed centers.

As summarized in my response to a previous question, if we face a situation that requires us to choose between losing some center core grants or seriously depreciating the value of peer-review recommendations by invoking large downward negotiations, we would reluctantly be forced to choose the former option. Most experts fear that choosing significant downward negotiations in order to preserve the number of centers is self-defeating in the long run.

ENROLLMENT OF WOMEN IN NCI-FUNDED CLINICAL TRIALS

Question. The General Accounting Office is conducting an investigation to determine the extent to which women are excluded as subjects from clinical trials. In 1987 NIH implemented a new policy that requires researchers to provide a rationale if they plan on excluding women from a study. The GAO report will be evaluating the effect of the new policy on the inclusion of women in study populations. Many medical treatments used on women are based on research which was conducted entirely on male subjects. What is NCI's policy on the enrollment of patients in clinical trials?

Answer. The most important factor determining enrollment of any patient onto a clinical trial sponsored by NCI is the patient's eligibility for that trial. Eligibility criteria encompass the following considerations:

- verification that the patient has the appropriate type and stage of cancer for that particular study;

- absence of any other medical condition that would impair the ability of the patient to tolerate the proposed treatment or impair the investigator's ability to evaluate the results of that treatment; and

- the ability of the patient to understand and comply with treatment and followup provisions of the study.

There is no gender bias implied or stated in any NCI protocol. Obviously, clinical trials involving diseases specific to one sex or the other, such as testicular or ovarian cancer, are restricted to patients of that sex. For diseases which affect both men and women, patients of both sexes are included in the clinical trials.

Question. To what extent are women excluded as patients?

Answer. Women have never been excluded from NCI-sponsored clinical trials. Gender is taken into consideration only for those cancers that affect a single sex such as prostate or ovarian cancers. It is also considered as a variable during analysis of the results of a clinical trial to determine whether it influenced the response or survival in patients treated with a new therapy.

Question. What progress has been made in identifying gender differences in disease etiology, course and treatment?

Answer. Males appear to be at a disadvantage when it comes to survival from cancer. The five-year relative survival rate for all sites combined is 55.9 percent for females but only 45.1 percent for males. This differential may be explained in part by the difference in the mix of sites for males when compared to females. Lung cancer is a highly lethal disease, more common in men (although women are catching up). Nevertheless, even for some of the cancer sites which are common to both, the males still have a lower survival rate:

	Males	Females
Lung & bronchus	11.6%	16.0%
Oral cavity	49.1	54.8
Stomach	15.8	19.2
Melanoma	75.9	86.5
Hodgkin's disease	74.1	78.2
Non-Hodgkin's	49.7	51.8

The survival differences for lung, oral cavity, stomach and melanoma persist even when limited to localized stage of disease.

For cancer of the colon/rectum, the survival rates are similar between males and females, 55.2 percent versus 55.6 percent, respectively. For cancer of the urinary system, males tend to have the survival advantage.

For all cancer sites combined, the cancer incidence rate (1983 to 1987) is higher in males than in females: 428.5 per 100,000 for males and 329.9 for females. Males have higher incidence rates (per 100,000) for nearly every cancer site which is common to both:

	Males	Females
Oral cavity	17.3	6.5
Stomach	12.1	5.4
Colon/rectum	61.2	43.4
Larynx	8.4	1.6
Lung & bronchus	84.2	35.6
Melanoma	11.5	8.9
Urinary bladder	29.5	7.4
Kidney & renal pelvis	11.3	5.3
Non-Hodgkin's	15.2	10.4
Hodgkin's disease	3.3	2.3
Leukemias	13.1	7.7

Similar differences are also seen for cancer mortality by gender.

Gender is one of many variables affecting cancer incidence and mortality that is analyzed by means of clinical trials. In some situations, it has turned out to be an important criterion in evaluating the benefits derived from specific therapies. For instance, scientists working in NCI's Navy Medical Oncology Branch have reported that women who are diagnosed with small cell lung cancer survive longer than men similarly diagnosed although both are given the same treatment regimens.

The reasons underlying these sex-specific observations are unclear at present. In some situations, gender differences may be seen in a clinical trial due to chance-variation alone. Perhaps they may be related to hormonal factors or to other influences that have yet to be defined. Preliminary analyses from a special study on survival differentials also indicate that coping strategies for males and females are different. NCI will continue to explore the role played by gender differences as they affect cancer etiology and treatment options in order to determine how to make optimum use of these differences with respect to cancer therapy.

FUNDING IN CANCER RESEARCH

Question. Many cancer specialists are concerned that shifts in funding and manpower from cancer to AIDS is seriously undermining the Nation's effort to conquer cancer. For example, a significantly smaller percentage of new cancer research proposals approved by review committees will receive funding compared with the mid-1970s. AIDS research has grown from 0.3 percent of NCI's budget in 1982 to 9.2 percent in FY 1990. The departure of many senior officials has left NCI with critical vacancies. Has the increasing percentage of NCI's budget devoted to AIDS research seriously affected the Institute's ability to fund promising new cancer research?

Answer. As you know, cancers do occur in patients with AIDS so we have more than a passing interest in AIDS. Immunosuppression, such as that seen in AIDS, is associated with the development of several kinds of cancer. The programs being proposed by the Cancer Institute for support with AIDS dollars will permit expanded activity in such areas as vaccine and drug development as well as immunologic and virology efforts. At the same time, the increase proposed for the cancer activities of the Institute will permit us to expand and accelerate research efforts in cancer prevention, diagnosis and treatment. With the explosion of knowledge in biomedical research that has occurred in the past few years, the opportunities have never been greater and we will continue to support the most meritorious research. Given its special scientific expertise, coupled with its historical commitment to retroviral research and new drug development, the NCI is a unique world resource for defeating cancer and AIDS.

Question. Has the emphasis on AIDS research at NCI affected the Institute's ability to recruit scientists and physicians to fill vacancies within NCI?

Answer. I do not believe that the emphasis on AIDS research has had a direct impact on our ability to recruit scientists and physicians. Indeed, the NCI offers its staff unusual opportunities to take new ideas from cancer research into AIDS research and vice versa. The scientific opportunities for researchers at the NIH, and the NCI in particular, are unique. Salary competition is a serious force in blocking recruitment and retention of established investigators. This is true for both the civil service and the commissioned corps of the Public Health Service, particularly for established researchers.

Question. Have the lower salary levels at NIH made it more difficult to attract scientists and physicians to fill position vacancies at NCI?

Answer. The NCI is not exempt from the overall pay discrepancy between the Federal and private sectors for white collar employees, and continues to experience difficulty in the recruitment and retention of senior scientific staff.

Highlighting this situation, the 1988 report from the White House Council's Federal Laboratory Review panel noted the following: "The inability of many Federal laboratories -- especially those under civil service constraints -- to attract, retain and motivate high-quality scientists is alarming. There are many reasons for this difficulty but the main one is noncompetitive pay and benefits compared with industry and universities. The National Institutes of Health has the largest difference between the Federal pay ceiling and the private sector earning power of specialized academic physicians." The pay gap has not noticeably changed since the release of that report.

Even though the scientific attractions and prestige associated with such a position at NCI are attractive, it is unrealistic to expect prominent cancer researchers to continually surrender tenure and lucrative compensation packages to accept offers of employment with NCI. It is desirable that salary and compensation packages be established so NCI can compete for the scientific talent needed to lead the Institute in its battle against cancer. The President's Budget addresses this need by requesting the authority to establish ten endowed chairs for eminent scientist researchers. These positions would allow salary compensation to exceed current caps -- up to 150 percent of Executive Level II.

CLINICAL TRIAL ENROLLMENT

Question. In June 1988, NCI instituted a promotional campaign involving seminars, feature stories in the news media and making information on clinical trials more accessible to patients and physicians. The target was to enroll 50,000 new patients in trials each year by 1992. NCI will focus initially on enrolling more patients for studies of treatment for bladder cancer, colon cancer, rectal cancer and non-Hodgkin's lymphoma. These cancers were given priority because they affect large numbers of people or they have the potential of being extremely responsive to the latest therapies.

How successful has NCI's effort been to increase patient participation in clinical trials?

Answer. Clinical trials are one foundation stone of the NCI. In 1974, there were 21 groups entering 19,000 patients onto clinical trials. In 1988, the number of patients on therapeutic clinical trials increased by two-thirds to 31,554, even though the absolute number of Clinical Cooperative Groups decreased to 11. In 1989, the patient population accrued onto clinical trials was 31,518 patients. Several important points may be made about the above figures.

- The Clinical Cooperative Group system is becoming more efficient. There are now fewer Clinical Cooperative Groups, yet there are more patients on clinical trials. Although fewer clinical trials are being conducted now, more patients are accrued at a faster rate onto each study.

- Studies are becoming increasingly sophisticated. Therapies being tested are often multi-modal, involving surgery, radiation, chemotherapy, and/or biological therapies. More non-therapeutic studies are being conducted. For the most part, these involve laboratory correlations of clinical studies.

- A system of High Priority Trials has been set up to hasten completion of studies that are of particular importance and are likely to result in significant advances in cancer therapy.

INTERLEUKIN-2

Question. In December 1985, there was extensive media coverage of a new experimental treatment involving the use of a natural substance, interleukin-2 (IL-2), to stimulate the body's immune system against cancer. In December 1986 another report on the experimental IL-2 treatment was published along with an editorial challenging the work and severely criticizing the amount of attention the new treatment received. Critics charged that the reports were premature, the treatment very expensive, the side-effects too severe and the benefits transient and uncertain. Modifications of the original treatment have achieved dramatic success against skin cancer without as many severe side effects. What is the current status of the new cancer treatment developed by Dr. Steven A. Rosenberg?

Answer. Dr. Rosenberg and his colleagues in the Surgery Branch, NCI have administered 1,039 courses of high-dose Interleukin-2 (IL-2) to 652 cancer patients. Of these patients, 596 had metastatic cancer and had either failed standard therapy or had no other effective therapy available. The other 56 patients with melanoma, renal cell carcinoma, or colorectal carcinoma were treated in the adjuvant setting. These patients have been treated with IL-2 alone or in combination with lymphokine activated killer (LAK) cells, tumor infiltrating lymphocytes (TIL cells), monoclonal antibodies, or other cytokines such as alpha-interferon or tumor necrosis factor. Approximately 10 percent of patients with advanced renal cell cancer or melanoma had complete regression of their tumors. An additional 20 percent had objective partial remissions. More than half of those patients who obtained complete remission have not had their tumors recur, with followup in some individuals for more than five years. In a prospective randomized trial comparing treatment with LAK and IL-2 to that with IL-2 alone, the overall response rates were similar although the incidence of complete responses appeared to be higher in patients receiving LAK and IL-2. Under a special "modified Group C" arrangement between the FDA and NCI, LAK cells and IL-2 or IL-2 alone are now available through regional cancer centers for those individuals with metastatic malignant melanoma or renal cell carcinoma who are not enrolled on a clinical trial.

TIL cells have been developed in an attempt to improve upon the antitumor activity seen with LAK cells. The tumor infiltrating lymphocytes are grown from immune cells found in a patient's tumor. Dr. Rosenberg and colleagues reported on the results obtained in 20 patients with malignant melanoma who were treated with TIL and IL-2. Nine out of 15 patients who were previously untreated and two out of five who had previously received IL-2 responded to this therapy (a 55 percent overall response rate). Current trials being conducted in the Surgery Branch, NCI are expanding on that experience, examining the use of TIL cells with other biological response modifiers.

Over the past 10 months, NCI investigators have begun gene transfer trials using TIL cells. A gene encoded for resistance to the antibiotic neomycin is inserted into a fraction of the TIL cells given back to a patient. These altered TIL cells are then tracked through the body to determine tissue and tumor distribution of TIL cells as well as TIL cell survival. To date, eight of a planned 14 patients have received transduced TIL cells. Data obtained from these patients indicate that transduced TIL cells are detectable in the bloodstream for up to 21 days and are detectable in the tumor for more than 64 days after administration. Future gene transfer studies will look at the transduction of alpha-IFN, IL-2, and/or TNF genes into TIL cells in an attempt to augment the antitumor activity of this therapy.

Question. What is the status of other immune system modulators, such as tumor necrosis factor and interferon, in the treatment of cancer?

Answer. Although licensed in this country for the treatment of a rare disease known as hairy cell leukemia and AIDS-related Kaposi's Sarcoma, investigational studies with alpha-IFN in a variety of disease types are still being pursued. Over 60 percent of patients with chronic myelogenous leukemia obtain a complete remission with alpha-IFN. Some of these responses are associated with normalization of the chromosomal abnormality associated with the disease. However, the complete responses may not be durable. Combinations of alpha-IFN with other cytokines, such as gamma-IFN, are currently being evaluated in Phase II studies of CML. Studies using alpha-IFN in renal cell carcinoma, melanoma, and ovarian cancer are underway. The use of alpha-IFN with the cytotoxic agent 5-fluorouracil (5-FU) has recently been reported to be quite effective in the treatment of individuals with metastatic colon cancer. Scientists at the Albert Einstein Medical Center in New York treated 30 patients with this combination and reported a 43 percent response rate for the entire group, and a 76 percent response rate for those individuals who had not received any prior chemotherapy. Confirmation of these results is pending the completion of a large scale study being performed through the Clinical Cooperative Groups.

Phase II testing of tumor necrosis factor (TNF) has not demonstrated significant antitumor activity when TNF is given as a single agent in any malignancy. However, based on promising preclinical data, other specific areas of interest that are being pursued include using TNF with antitumor agents which act in fundamentally different ways in an attempt to improve the antitumor activity of these agents. The antitumor activity of this agent may be optimized by using alternative routes of administration. A Phase I trial of intravesical TNF, that is, applying TNF directly into the bladder, has begun for the treatment of early stage bladder cancer.

The Biological Response Modifiers Program (BRMP) of NCI's Division of Cancer Treatment is actively pursuing a series of studies to identify and further characterize new biological response modifiers. Recently discovered, Interleukin-8 (IL-8) is a protein secreted by a variety of cells and is believed to be involved in controlling the migration of immune cells to sites of infection or cancerous growth. A second agent being studied is perforin, a highly toxic molecule secreted by natural killer cells. This molecule has recently been shown to possess the capacity to insert itself into the membrane of tumor cells, leading to a breakdown in the surface membrane of the cell and, finally, cell death. Current efforts are focused on identifying the ways in which perforin levels are controlled in the cell and in understanding perforin's mechanism of action. These are but two of the many promising biological response modifiers under development.

ACCOMPLISHMENTS

Question. The nation has invested considerable funding for cancer research over the years. Gains have been shown in many areas over the past few years. Briefly, Doctor, can you give me the top three or four accomplishments of the past year?

Answer. As you know, cancer is a complex, diverse, and formidable disease and yet we have effective treatments and marked improvements in cancer mortality in young children and in adults under age 65. This year, lung cancer mortality rates dropped from the mid-1970s to the mid-1980s -- a dramatic 29 percent drop in white men aged 35 to 44 -- and experts predict they will continue to drop -- this is believed to be the payoff of the basic research linking smoking to cancer and the subsequent public education campaigns on smoking cessation and prevention. To offset this, however, we are losing ground in women with lung cancer.

Past and future progress in preventing and curing cancer are predicated on a broad base of biomedical research. This has been a year of high scientific achievement in cancer research.

To illustrate: two NCI scientists working with colleagues from the National Heart, Lung, and Blood Institute made medical history by inserting new genetic material into human cells in the laboratory and then placing the cells back into a patient. They were then able to track the presence of genetically engineered cells in the patient's circulatory system for several months. These experiments built on previous NCI research on natural biological elements within the body that fight cancer. As a result, we are now on the threshold of new gene therapies to correct or replace missing or damaged genes that cause devastating illnesses -- such as severe childhood immune deficiency.

NCI also filed Investigational New Drug (IND) applications for eight drugs and 11 new biological response modifiers -- many for previously untreatable cancers or AIDS. Recently, NCI-supported scientists have made a number of important genetic discoveries. In particular, there have been new insights into the role of tumor suppressor genes. The NCI-Navy Medical Oncology Branch has found that certain genetic abnormalities play an important role in the genetic events that culminate in lung cancer. An NCI-grantee at Johns Hopkins has shown that an accumulation of complex genetic alterations is associated with the progression of colorectal tumors from benign adenomatous polyps to frank carcinomas. This lays the groundwork for new advances in the early diagnosis and treatment of colorectal tumors.

Other genetic findings include the location of the gene for familial malignant melanoma on chromosome 1. About 10 percent of all malignant melanoma cases fall into this category. Five proteins involved in metastasis, the wild spread of cancer from the original tumor, have been identified. These proteins may be involved in positive and negative regulation of tumor invasion and metastasis and include the laminin receptor, autocrine motility factor, NM23 metastasis suppressor protein, type IV collagenase, and the newest discovery TIMP-2 metalloproteinase inhibitor. These discoveries add to the knowledge needed to control this often lethal process.

NCI-supported scientists have discovered more about the human papilloma virus and its attack on suppressor cells in the development of cervical cancer, which is similar to the process at work in squamous cell cancer of the oral cavity.

NCI-supported research is developing new adjuvant therapies. These employ the use of chemotherapy or hormonal therapy after surgery. This year, NCI-supported scientists showed that deaths from a type of advanced colon cancer could be reduced a third, using an adjuvant treatment combination of levamisole, immune stimulant, and 5-fluorouracil (5-FU) in treating Dukes' C colon cancer. There will be approximately 110,000 new cases of colon cancer in 1990 and 21,000 will be the Dukes' C stage. Of these, about half will recur and eventually die if left untreated.

NCI-supported studies showed that many women with node-negative breast cancer could benefit from chemotherapy or hormonal therapy after surgery. About 70,000 of the 142,000 women who are diagnosed each year with invasive breast cancer may benefit from this treatment advance. Clinicians have known that up to 30 percent or more of node-negative patients ultimately have recurrences of their cancer and often die of these recurrences. These adjuvant therapies can significantly reduce the rate of recurrence and hopefully will not only give them disease-free years, but also extend their lives.

Currently there are promising adjuvant therapies being developed for patients with bladder, head and neck cancers.

A number of new diagnostic tests which measure tumor secretions, oncogenes or DNA, help identify the breast cancer patients who can most benefit from specific treatments. These tests come directly from basic cancer research and have been quickly developed to help patients.

Other basic research discoveries such as the finding that the N-myc oncogene is amplified in the neuroblastomas of pediatric patients and that the HER-2neu oncogene has been confirmed not only in breast cancer, but also in ovarian cancer, are the basis of new diagnostic and prognostic tests.

In addition to the INDs mentioned above, new combinations or new uses of old drugs are being developed. Recent research at the NCI-funded Cancer Center at the University of Arizona demonstrated that adding verapamil, a calcium channel blocker used in cardiology, to the usual chemotherapy regimen helped to reduce drug resistance in patients with refractory myeloma and non-Hodgkin's lymphoma.

NCI-supported Cancer Centers play a vital role in not only basic research, but in the clinical trials needed to develop new treatments and approaches and in bringing the best of new cancer treatment to their communities. The Cancer Centers provide an important resource in identifying regional cancer problems and in focusing research, prevention and treatment to aid their areas.

NCI has reached out to help people deal with cancer. The Cancer Information Service, reachable by a toll-free 1-800-4-CANCER number, answered over 500,000 questions. The Physicians Data Query, a computerized database, provided state-of-the-art information to physicians and referred tens of thousands to NCI-supported clinical trials where patients could receive experimental or state-of-the-art cancer treatment. Over 500,000 patient education brochures were mailed to give cancer prevention or screening information or to help patients understand cancer, cancer treatment and to help them in dealing with side effects and other aspects of their treatments.

Turning to achievements in AIDS research and in related areas of cancer, NCI-supported scientists have identified new families of viruses, such as the human retroviruses involved in AIDS and some leukemias. The long-term commitment of NCI to the study of such viruses has contributed to success in preventing and treating AIDS. In addition, such viruses are involved in certain chronic liver and neurologic diseases, so the value of this research extends beyond cancer.

NCI-supported scientists are making important contributions in AIDS drug and vaccine development. NCI is leading the development of treatments for children with AIDS.

Combining physics and math, scientists have constructed a three-dimensional model of the crystal structure of the HIV-1 protease using the supercomputer at the NCI's Frederick Cancer Research Facility. Knowing the exact structure of this important molecule will allow for the design of a molecule to block the reproduction of the AIDS virus.

Recently, scientists at NCI's Frederick Cancer Research Facility have completed important steps in the development of a vaccine for AIDS. Among these steps has been the identification of target sites on the HIV envelope protein that are most effective in eliciting an immune response which will help with the development of a vaccine. Other approaches have included altering genes in the HIV virus to make it impossible for the virus to reproduce.

GENE TRANSFER

Question. The gene transfer work that has been reported is very exciting. Can you update us on the current status of the gene transfer work of Drs. Rosenberg, Blase and French?

Answer. Tumor infiltrating lymphocyte (TIL) cells are special cells that can be artificially grown out of a patient's cancer, and in turn, such cells can destroy the cancer. Currently, the researchers are evaluating the uptake and distribution of transfected TIL cells throughout the body and determining the specificity of TILs to a patient's tumors. (A transfected cell is one that is artificially carrying a foreign gene). Analysis of the data accumulated from the first patients treated with the therapy has revealed that transfected TIL cells remain detectable in the blood stream for up to 21 days, move into tumor cells with the same efficiency as non-transfected TIL cells, and are detectable in tumor tissue for at least 65 days after infusion. After 12 patients have been treated and fully evaluated, permission will be sought to transfect TIL cells with genes that code for interleukin-2 (IL-2), tumor necrosis factor, (TNF) or alpha-interferon in an attempt to enhance their antitumor activity. IL-2 is required for the ex vivo creation of TIL cells in tissue culture. Insertion of the IL-2 gene into TIL cells may not only enhance TIL tumor-killing ability, but also recruit and stimulate other nearby cells which may augment this effect. Levels of circulating TNF in LAK- or TIL-treated patients has been associated with clinical response to adoptive immunotherapy; those patients with elevated levels of TNF were more likely to respond to treatment than those who did not. Insertion of the TNF gene into TIL cells may stimulate TIL activity as well as mediate other direct and indirect antitumor effects. Alpha-interferon increases the major histocompatibility complex (MHC) on tumor cells. TIL activity appears to be related to MHC levels with those tumors having the highest MHC level being the most susceptible to TIL-mediated tumor destruction. By inserting the alpha-interferon gene into TIL cells, MHC expression by the tumor may be increased, making the tumor more sensitive to the effect of the TIL cells.

The potential of gene transfer therapy extends well beyond cancer. Diseases that are caused by specific genetic defects or deletions, such as sickle cell anemia, cystic fibrosis, and alpha-1-antitrypsinase deficiency (leading to severe lung damage) are prime candidates for gene transfer therapy. By replacing the damaged or missing gene with a normal, fully-functioning gene, these diseases can conceivably be cured. The gene transfer experiments described above may be the first step in making such a therapy a reality.

FLUORIDE

Question. Recently, news accounts have reported a potential influence of fluoride on the health of the American people. What can you tell us about the carcinogenic potential of fluoride in the drinking water?

Answer. We treat all such reports seriously, and will respond with facts and informed opinion as quickly as possible. A recent National Toxicology Program (NTP) study (as yet not peer-reviewed) of sodium fluoride in F344/N rats and B6C3FI mice of both sexes gave some evidence of osteosarcomas developing in male rats at the intermediate dose of 45 ppm (as fluoride), 1/50; and at the highest dose 79 ppm (as fluoride), 4/80; none at 25 ppm and none in the controls.

The NCI previously studied and published (Journal of the National Cancer Institute 57: 757, 1976) a study on cancer mortality and incidence statistics for U.S. counties 1950 to 1969. No trends for any form of cancer, including bone cancer, could be ascribed to the consumption of water that is artificially or naturally fluoridated. It is worth emphasizing that in several areas of the country, drinking water is fluoridated by nature. Several other studies (a total of 21) in the U.S. and abroad, especially in Great Britain, are remarkably consistent in finding no evidence of overall or site-specific excesses of cancer that could be attributed to the level of fluoride in drinking water. This led to the conclusion that "variations geographically and in time in the fluoride content of water supplies provide no evidence of an association between fluoride ingestion and mortality from cancer in humans." We currently have no reason to doubt this conclusion. A few potential disadvantages of the available data should be noted, however. All are descriptive studies based on geographic comparisons. While they are strong studies because of the widespread and often abrupt changes in fluoride exposure, they are nevertheless still based on correlational analyses that are subject to inherent limitations. Secondly, only one other study from England, in addition to the NCI study, included an evaluation of incidence as well as mortality data. While this is not a drawback for the evaluation of most sites, it is a possible concern for bone cancer (suspected on the basis of bioassay data), since this tumor may be theoretically misclassified as a cause of death because of the frequency of bone metastases from a variety of primary malignancies.

The NCI has recently made an examination of time trends in osteosarcomas from the Third National Cancer Survey (1969 to 1971) and the Surveillance, Epidemiology and End Results (SEER) program for the five geographic areas that were common to both surveys. By the end of 1969, the vast majority of the population covered by these five areas was drinking fluoridated water. Statistically speaking, these rates do not appear to be rising over this time period, and an analysis of age-specific patterns is now underway through 1987. Two further analyses are planned. First, the NCI will update its 1976 mortality study with data available now from the 1970s and early 1980s. Second, colleagues from the National Institute of Dental Research and Centers for Disease Control have agreed to provide NCI with the fluoridation status of the geographic regions covered by the SEER areas, at the county level.

When these data are in hand, the NCI will determine whether any meaningful epidemiologic comparisons are possible with the incidence data as can be carried out with the mortality statistics. The NCI hopes to have all analyses completed by June 1990.

CANCER INFORMATION

Question. Doctor, the American people are all very concerned with cancer; therefore we need to be sure they have the latest information. Tell us what NCI is doing to get cancer information to the public at large (private citizens).

Answer. As part of its legislated mission, the National Cancer Institute actively supports cancer information dissemination activities. NCI has placed an emphasis on working to ensure that the general public, as well as the primary-care physician and their representative professional groups, are afforded rapid access to up-to-date information regarding cancer prevention, detection and diagnosis, and treatment measures. Many initiatives have been implemented which are specifically directed at enhancing cancer information dissemination.

The Cancer Information Service (CIS), known to the public as 1-800-4-CANCER, is staffed by health professionals equipped to respond to public inquiries regarding cancer and to provide up-to-date information. It consists of a nationwide network of regional offices, 17 of which receive direct NCI funding and cover a combined population of 164 million in over 30 states. The remaining population of the U.S. receives coverage through a centrally located national office also funded by the NCI. Last year, CIS counselors answered nearly 500,000 calls; a total of over three million since 1976. Periodically, heightened public interest in specific cancer risk factors (e.g., Alar, radon, asbestos), will result in a flood of calls to 1-800-4-CANCER. Last year, over 200,000 letters were answered and 19 million pamphlets/brochures were distributed directly to individuals or in bulk to hospitals and other organizations. This year, data was analyzed from 2.2 million calls placed from 1983 through 1988. Television was the most frequently cited source for learning about the CIS for prevention information.

In addition to providing a direct response to general public inquiries, the regional offices support NCI's outreach activities and conduct cancer education programs to meet specific regional needs. For example, in support of NCI's mammography initiative in 1989, the CIS launched, through the regional offices, a major coordinated nationwide media campaign. An evaluation of the CIS is now underway; topics under study include smoking prevention/cessation and the use of mammography. This evaluation will provide guidance to the Institute in the design of its cancer prevention campaigns, which use the CIS as a referral point for persons seeking prevention services, advice and information.

Breast cancer screening is recognized as an efficacious, life-saving technology that is vastly underused. NCI has launched a network of intervention studies known as the Mammography Consortium, to evaluate health promotion strategies for improving the utilization of mammography, clinical and self breast examinations. Seven studies are now underway in various communities; besides completion of baseline surveys, one year of intervention has been completed in five of the seven communities. The studies have drawn attention to marked differences in perceptions of mammography commonly held by women as compared to those held by physicians. The surveys showed that the most common reason given for not obtaining a mammogram was that the woman had not thought about it and/or there was no problem. The next most common reason was that physicians had not recommended it. Cost of mammograms, inadequate insurance coverage, and equivocal radiology reports were the three biggest barriers to mammography referral. Efforts to ameliorate these barriers and reconcile the different perceptions are underway in the seven Mammography Consortium communities.

For the last two years, NCI has collaborated with Giant Food, a regional supermarket chain in the Washington, D.C. metropolitan area, in a project called "Eat for Health". The project is designed to help food shoppers choose foods and eating patterns to reduce the risks of diet-sensitive cancers. The program includes a variety of in-store information devices and radio and television advertising designed to improve consumer understanding about foods, cancer and overall health. During the past year, this program has won three national awards, and has been cited as an example of an exemplary community nutrition education program. A meat and poultry intervention was successfully implemented in the Washington area stores this year; 150,000 bulletins were distributed monthly throughout Giant's 105 metropolitan Washington, D.C. stores.

The worksite is an important channel for creating behavior change aimed at reducing cancer risk, allowing for occupational exposures and lifestyle factors to be addressed in an integrated fashion. Moreover, existing social structures can be used to support individual behavioral change. This year NCI initiated a study to design, implement and evaluate the effects of nutrition, screening, and tobacco control interventions on the cancer-related health behaviors of workers and on the worksite as a unit. Because little is known about how to effectively modify eating behavior in the work environment, nutrition was given a high priority. Three intervention projects in Florida, Massachusetts and Texas, as well as a coordinating center, will be funded over a five-year period.

Initiatives which seek to minimize the lifetime risk of cancer are extremely important. Because of this, NCI places high priority on the development and evaluation of strategies to positively influence the diet and smoking-related behavior of our youth. One of the project aims is to enhance the diffusion and integration of tobacco education curricula into selected school systems. NCI has now collected baseline measures on student knowledge, attitudes and behavior related to tobacco use and the utilization of tobacco education topics in the school curricula. Another youth activity involves a joint effort between the American Cancer Society (ACS) and the NCI for the development of a nutrition education curriculum to lower cancer risk for intermediate and secondary school children. The curriculum has been field tested and is currently being distributed across the country by local ACS offices. A companion effort to this curriculum is the promotion of a newly developed nutrition guide for school food service managers.

INTERNATIONAL ACTION

Question. Doctor, a lot has changed in Eastern Europe and Russia during the past six months. What has the NCI done in response to these new opportunities?

Answer. Within NCI, the Office of International Activities works to further scientific collaboration between the United States and other countries. This office provides assistance to visiting scholars, sets up joint scientific programs, and works with international organizations. Within another component of NCI, the International Cancer Research Databank Branch (ICRDB) utilizes state-of-the-art technology to amass, organize, and disseminate research data. The NCI actively promotes this exchange of data worldwide among cancer researchers and practicing physicians. Looking specifically at Eastern Europe and Russia, more collaboration is taking place; expectations are high that communication regarding cancer research will continue to grow more open.

USSR: Collaboration in cancer research has expanded dramatically. The Soviet coordinator for the U.S.-Soviet bilateral program has proposed many more visits of Soviet cancer researchers to American laboratories; furthermore, the Soviet government now permits their scientists to visit U.S. laboratories for longer periods of time. I have met with Soviet Ambassador Dubinin, and he is most interested in fostering these relationships.

The All-Union Cancer Research Center (AUCRC) in Moscow is conducting clinical trials in parallel to some being conducted here. A treatment protocol using cisplatinum in testicular cancer is now nearly at full patient accrual and three additional protocols dealing with colon and breast cancer were started last year. Working in collaboration with these studies, an NCI investigator has just returned from a two-month visit to Moscow. An American delegation of prominent cancer researchers will be visiting Moscow this March to assess the progress of these treatment studies. The Soviet Union has traditionally exhibited strong excellence in mathematics and physics research. We are exploring appropriate cancer-related collaborations in such areas of excellence.

Preliminary discussions are underway exploring the feasibility of establishing two U.S.-Soviet cancer institutions, one in Moscow and one in the Soviet Far East. The NCI is prepared to assist the Soviets in the training of their future scientific and clinical faculty. Long-term training of Soviet scientists in the West will acquaint them with newer techniques which should translate into more use of state-of-the-art treatment regimens and foster further collaboration.

It is likely that a number of possible new initiatives dealing with cancer information and Eastern Europe will be the topic of a President's Cancer Panel meeting in the fall of this year.

NCI is preparing to provide Eastern European cancer institutions, including those in the USSR, its Physician Data Query (PDQ) and CANCERLIT databases using compact disc technology. The data-bases provide the latest information in both basic and clinical cancer research. NCI envisions a cooperative demonstration and evaluation project at a selected number of East European institutions, including the AUCRC in Moscow. In addition, Soviet researchers have expressed interest in products manufactured by U.S. biotechnology and pharmaceutical industries, and in the American publications related to cancer research, treatment, and prevention.

Poland and Hungary: Bilateral cancer programs between the U.S. and Hungary and Poland have been active during the last decade. A U.S.-Hungarian workshop was held last fall in Budapest to evaluate the 10 year-old program. Its continuation was endorsed, and the Polish and Hungarian coordinators for the programs have enthusiastically responded to NCI's initiative of providing the PDQ and CANCERLIT databases.

Other Eastern European Nations: The most dramatic changes are taking place in our relations with cancer research institutions in East Germany, Czechoslovakia, and Yugoslavia. Very few contacts were permissible in the past between cancer research scientists from these nations and their American counterparts. The first scientific exchanges to NCI and other U.S. laboratories have now been scheduled for this spring.

RECOMMENDATIONS

Question. Dr. Broder, a year ago the Institute of Medicine made its report on cancer centers that was required by the Congress. Could you tell us what were the recommendations made by the Institute of Medicine report, and what steps you have taken to deal with those recommendations?

Answer. The IOM Report recommended that the National Cancer Institute (1) strengthen core support of cancer centers in order to exploit fully the application of research advances; (2) take immediate steps to avert a crisis in the funding of cancer centers in FY 1989; (3) work with NIH, the Secretary DHHS, and congressional appropriations committees to develop an adequate budget for FY 1990; (4) develop a systematic program plan for the Cancer Centers Program; and (5) determine how best to increase representation of the Cancer Centers Program in NCI planning and decision-making processes. The IOM Report recommended an immediate infusion of six million dollars into the centers program. It also recommended that centers be moved administratively.

With regard to the FY 1989 budget, the NCI maintained all high-quality centers at 85 percent of peer-review recommended levels. NCI will strive to support the most meritorious centers in FY 1990, within available funds.

At this time, options are being considered that will maintain the viability of as many cancer centers as possible without reducing individual Center budgets below the level of operational stability. Final funding decisions will be made sometime in April after all critical peer review results are obtained.

With regard to (1), (4), and (5) above, the National Cancer Institute is developing a 5-Year Plan for the Cancer Centers Program. The development of the first complete draft of the plan involved staff from all NCI program areas, six cancer center directors elected by their peers, and Dr. Sydney Salmon, who is director of the University of Arizona Cancer Center and currently president of the American Association of Cancer Centers. The draft plan has been distributed to all cancer center directors and members of Boards of Scientific Counselors for comment and is in the first stages of review by the National Cancer Advisory Board. The plan addresses every aspect of cancer centers from basic research to clinical research and from technology transfer to outreach activities. The ad hoc committee of cancer center directors will remain advisory to the Cancer Centers Program, and an internal committee with representation of all NCI Divisions will be used to ensure that the Cancer Centers Program serves as a key element for facilitating the transfer of research findings to the community at large. The purpose of the 5-Year Plan is to create a stronger, more effective centers program that takes maximum advantage of the individual strengths of cancer centers through better two-way communication between the NCI and cancer centers in planning and priority setting processes and through the development of additional tools to facilitate technology transfer and outreach activities to underserved populations.

Internally, the NCI has reorganized and placed the Cancer Centers Program and other resource programs under an Associate Director in the Division of Cancer Biology, Diagnosis and Centers. This program is being provided more direct access to the Executive Committee of the NCI to ensure that all issues related to cancer center support grants are considered thoughtfully and completely within existing budgets.

CANCER CENTERS

Question. Dr. Broder, please tell us about the cancer centers. What is the level of funding that is proposed by the Administration budget, and what funding level, in your view, is required to carry on a good cancer centers program?

Answer. The NCI currently supports about 56 cancer centers. Cancer centers (basic, clinical, and comprehensive) are a major cornerstone of the Institute. They support crucial interdisciplinary research, community service, and outreach. The President's Budget proposes that cancer centers be supported at the level of $103.0 million. With this level we will attempt to fund the same number of centers that were supported in FY 1989, but with at least a 15 percent reduction to competing centers; continuing centers will be paid at committed levels. However, it is possible, based on the specific mix of new and competing core grant applications, that a reduction in the number of funded centers will take place. This might be necessary to avoid very severe downward negotiations. The FY 1991 By-Pass, NCI's professional judgment budget, supports center requirements at $144 million. Within this By-Pass Budget, NCI would restore funds for centers phased out in 1989 and 1990, which are expected to resubmit in FY 1991; pay continuing centers at committed levels and competing centers at recommended levels. In NCI Year 2000 Goal, plans called for increasing the number of cancer centers by 50 percent. The By-Pass for 1991 adds approximately five new centers to be supported at some of the most prestigious cancer research institutions in the country. Targeted programs would be supported in prevention initiatives, clinical trials, minority demonstration centers, the populace over age 65, and the underserved.

Question. What is happening with the cancer centers in terms of the number of cancer centers that have been or will be lost because of insufficient funds for fiscal year 89, 90, and 91?

Answer. During FY 1989 we phased out four existing cancer centers. This was necessary in order to provide the remaining centers with an operating level more consistent with their peer reviewed approved level. Competing centers were then funded at approximately 85 percent of their approved amount. For 1990, we are reviewing our funding policy. We are planning on supporting the same number of centers as in 1989, as suggested in last year's Senate report. However, this will require reductions to 80 to 85 percent of the recommended level. For 1991 we will need to carefully review the program and support those centers that are of the highest program priority. We are very concerned about depreciating the individual-core grant funding level based on peer-review.

Question. Dr. Broder, in our opinion, it would appear that correcting the problems with cancer centers, as outlined in the IOM report, might require a greater allocation of funds than that included in the Administration's budget. Could you identify for us how you would use additional funds above and beyond the Administration's budget should the Congress choose to appropriate more than that called for in the budget?

Answer. The FY 1991 By-Pass, NCI's professional judgment budget, supports center requirements at $144 million. Within this By-Pass budget, NCI would restore funds for centers phased out in 1989 and 1990, which are expected to resubmit in FY 1991; pay continuing centers at committed levels and competing centers at recommended levels. In addition, the geographic and demographic expansion of the centers program would require the initiation of new centers throughout the Nation, including those in underserved regions. Within available funds, five additional new centers would be awarded. One point is worth stressing: linked to the expansion of cancer centers is the necessity to balance its expansion with other components of the National Cancer Program. For example, a significant portion of investigator-initiated research, funded through the research project grant mechanism, is conducted at institutions with cancer centers. As a part of the emerging Five-Year Plan for centers, which is contained in the IOM Report you refer to, it is recognized that new opportunities in cancer research are created by additional support to other NCI support vehicles, including the research project grant category.

Other program expansions that would have a linkage with the centers activities would include prevention and clinical trials, education and training initiatives, as well as outreach components and information dissemination activities.

A balancing of funding among all mechanisms, with the advice of our advisory groups, would be appropriate for any additional funding. Centers are a crucial foundation stone of the NCI; however, other foundation stones (basic research through research project grants) and clinical trials must be kept in balance.

CLINICAL RESEARCH AND TRAINING

Question. Dr. Broder, could you tell us about the status of funding for clinical research and clinical training? What are the problems in this area in terms of funding?

Answer. **Treatment Research**: the National Cancer Institute has major responsibility for the prevention of cancer and for the discovery and development of new cancer treatments. The process of the discovery and development of new treatments requires both basic research as well as clinical testing. Drug discovery is largely supported by grant or contract mechanisms. Clinical trials receive their funding through contracts for the initial phases of testing; larger, multi-institutional trials in which new agents are compared to standard therapies are funded by cooperative agreements with the NCI. Thus, all potential funding mechanisms, including grants, contracts, cooperative agreements and intramural NCI research, have a role in the process of cancer prevention and drug development research. The 1991 treatment research budget estimate of $564 million represents a 3.7 percent increase over FY 1990. The NCI currently supports $227 million in AIDS and cancer clinical trials research, including intervention trials supported by the Prevention and Control Program.

The preclinical component of treatment discovery is multifaceted, involving both the empirical testing of natural products and chemicals, the rational design of new cytotoxic drugs, and the isolation of a variety of biological agents such as monoclonal antibodies and growth regulatory compounds. Once an active new agent is identified, it undergoes an intensive assessment of its biochemical mechanism of action, and pharmacologic and toxicologic properties.

Clinical treatment research expands upon the most promising leads developed in the preclinical program and evaluates these new treatments in patients with cancer. The testing of new treatments follows a logical course of progression. Phase I clinical trials establish the maximum tolerated dose, identify the optimal schedule of administration, and provide information on the side effects encountered with the new therapy. Phase II trials examine the efficacy of the new drug in various types of cancer, and Phase III studies compare the new treatment with the best standard therapy to see if the new therapy offers any advantages, in terms of greater activity or reduced toxicity, over the standard therapy.

Additionally, the National Cancer Institute has a goal, through Rehabilitation Research, of ensuring that cancer patients achieve the highest possible level of functioning and quality of life. This area of research addresses the protection and restoration of physical, psychological, social, and vocational functioning of patients, survivors, and their families. Research in this program seeks to identify techniques that will overcome barriers to the full utilization of currently available cancer therapies, thereby enhancing the application of state-of-the-art cancer management in the health care delivery system.

Training: in the area of clinical training, the NCI does not provide support towards obtaining an M.D. degree; however, there are several programs devoted to training and preparing M.D.s to pursue careers in research. These include the National Research Service Award (NRSA) program as well as research career development awards which are designed specifically for the research training of physicians. The majority of physicians receive research training through the NRSA program; in FY 1989 approximately 250 M.D.s were trained on NRSA awards. In addition, within the research career program, the NCI funded 11 preventive oncology awards, 45 clinical investigator awards, and 19 physician scientist awards. While some physicians receive training indirectly by taking part in various kinds of research grants, the above award mechanisms are the optimal, formal ways to train M.D.s for research careers. However, there are some obstacles related to the training of physicians. The first is that fewer physicians are choosing careers in research, largely due to the more lucrative options available to physicians who enter private practice. The second is that physicians as a rule do not receive the degree of training necessary to compete as effectively as Ph.D.s for research grant support. We are particularly concerned about training oncologists (cancer doctors) with expertise in prevention.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

EXTRAMURAL CONSTRUCTION

Question. Dr. Broder, will the National Cancer Institute have funding available in FY'90 for extramural construction? If so, how much and how many grants do you anticipate awarding?

Answer. The $1.5 million available in 1990 is intended to support routine preventive maintenance activities at the Frederick Cancer Research Facility (FCRF). In addition, the authority to assess the Institutes, centers and divisions for extramural construction was given to NIH for 1990. To date, NCI has been allocated $2 million of these funds to support two extramural construction grants with the best priority scores.

FUNDING FOR CANCER CENTERS

Question. Dr. Broder, does the budget for fiscal year 1991 include sufficient funds to support the existing cancer centers at the approved funding levels?

Answer. The FY 1991 President's Budget provides the same level for centers as was provided in FY 1990. Dependent on the peer review process, we plan to award about 56 centers, also the same level as FY 1990. Funding plans in FY 1991 require that NCI reduce competing centers up to 20 percent of their recommended levels; continuing centers will be funded at committed levels. It is important to stress that the exact number of centers and the downward negotiations factor is a function of the exact mix and funding requests of new and competing renewal centers that apply.

Question. If not, how much would the NCI need to fund the centers at their fully approved level?

Answer. NCI would require approximately $11 million, for a total of $114 million, in order to fund both competing and noncompeting centers at their recommended levels, as our best estimate of the needs in this mechanism based on FY 1990 and 1991 projections.

Question. Short of additional funding, what will the "downward" negotiation rate be for the centers in FY'91? What were the rates in FY'90 and FY'89?

Answer. NCI is still reviewing its FY 1990 funding options for centers. We are extremely sensitive to the problems currently being felt by center institutions, and in fact do not want to lose centers or to significantly negotiate them down. It is our hope that all meritorious centers will be funded in FY 1990. In FY 1989, competing centers were funded at 85 percent of their recommended levels; noncompeting centers were paid at committed levels. The funding for centers in the 1991 President's Budget would permit funding noncompeting awards at their committed level and competing applications at approximately 15 percent downward negotiations, but a 20 percent figure might well be necessary. The advice of our expert advisors is that it is better to fund centers at closer to the peer-reviewed level than to impose severe negotiations, even though some centers will not be funded.

Question. What action has the NCI taken to address the decline in funding to centers? How have the centers responded to declines in funding from their approved levels?

Answer. NCI is currently exploring ways to ensure that scientific excellence continues within the centers program. The NCI is developing, in concert with center directors, the National Cancer Advisory Board, staff from each of NCI's six divisions, and the president of the American Association of Cancer Centers, a 5-Year Plan for centers. The plan addresses every aspect of centers from basic research to clinical research and from technology transfer to outreach activities. The purpose of the 5-Year Plan is to create a stronger, more effective program that takes maximum advantage of the individual strengths of cancer centers through better two-way communication between the NCI and cancer centers in planning and priority setting processes and through the development of additional tools to facilitate technology transfer and outreach activities to underserved populations.

If given the choice, coupled with the issue of program balance across all NCI programs, NCI would opt to reduce the number of centers, as it is felt that negotiations below a certain point threatens the excellence of the individual centers and the total portfolio. If tough choices are necessary, we would hope that maximum flexibility for achieving the necessary balance between the number of core grants and the downward negotiation factor be provided.

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

STATEMENT OF CLAUDE LENFANT, DIRECTOR

BUDGET REQUEST

Senator **HARKIN**. Let us now go to Dr. Claude Lenfant, Director of the Heart, Lung, and Blood Institute.

Dr. **LENFANT**. Thank you, Mr. Chairman.

Senator **HARKIN**. I just wanted to see what you have here, $1.112 billion, a 3.75-percent increase.

Dr. **LENFANT**. That is correct.

Senator **HARKIN**. Please, proceed.

Dr. **LENFANT**. Thank you, Mr. Chairman.

In past years I have appeared before you and told you that our cardiovascular research programs have been very successful. Indeed, mortality rates from these diseases continue to decline.

For example, we can estimate that 425,000 additional cardiovascular deaths would have occurred in 1988 had the death rate not declined between 1967 and 1987.

Of course, this has happened because of our ever-increasing ability to diagnosis and treat cardiovascular patients, especially those with coronary heart disease.

However, there is a tradeoff for this success, and we must not be lulled into a false sense of security. It is now very clear from demographic shifts that the prevalence and, therefore, the burden of cardiovascular disease is increasing.

Our concern for this situation is matched only by our concern with the increased death rate from pulmonary diseases that we continue to observe year after year.

These problems, Mr. Chairman, can be solved only by intensified research to identify early those at risk of cardiovascular and pulmonary disease, and by developing more effective therapies.

PREPARED STATEMENT

My written statement describes an array of research avenues that we are actively pursuing on heart, lung and blood disease. Also mentioned are achievements with public health and cost saving benefits.

These accomplishments reflect the breadth of our program in basic, clinical and demonstration research. To conclude, I would like to underscore the contributions of our centers supported clinical research, which in our opinion has so greatly contributed to the health of the American people.

I would be pleased to answer questions, Mr. Chairman.

[The statement follows:]

STATEMENT OF DR. CLAUDE LENFANT

It is my pleasure to speak to you once again about the programs of the National Heart, Lung, and Blood Institute (NHLBI). Since its inception, the Institute has been strongly committed to disease prevention, a goal that has been greatly furthered by basic, clinical, and population-based studies designed to identify risk factors for cardiovascular, lung, and blood diseases. Interventions to reduce the impact of the three major cardiovascular risk factors--hypertension, cigarette smoking, and high cholesterol--have paid off handsomely in terms of reduced mortality. Findings from new studies are now bringing more precision to our indicators of risk for certain subgroups of the population. For example, the Framingham Heart Study recently reported results of echocardiographic studies that revealed increased left ventricular mass to be a powerful predictor of future heart problems in Blacks and in elderly persons. The recently initiated Cardiovascular Health Study, which focuses on individuals ages 65 to 90 years, is examining combinations of risk factors, such as elevated cholesterol, glucose intolerance, insulin resistance, and obesity, to identify patterns that may presage coronary events. The findings should provide important information for an age group in whom hypertension and high blood cholesterol are quite prevalent and yet are not as strongly associated with the risk of developing cardiovascular disease as in younger people. Significant public health benefits and cost savings are likely as we refine our ability to identify persons who will benefit from medical and lifestyle intervention and focus our efforts and resources where the return will be the greatest.

Evidence of benefits that can result from reducing serum cholesterol levels continues to accumulate. Two recent studies, one using drugs and the other using a combination of strict diet and behavioral changes reported that lowering cholesterol actually causes regression of atherosclerotic changes in arteries. These results underscore the public health gains to be realized by the National Cholesterol Education Program (NCEP). The NCEP "know your cholesterol number" message is reaching the community: in 1988, 66 percent of adults had their cholesterol levels measured as compared with 35 percent in 1983. The interest of people in knowing their blood cholesterol levels is reflected in increased public cholesterol screenings. To be successful, cholesterol screening must lead ultimately to a reduction in the risk of coronary heart disease (CHD), an objective that can be accomplished only if proper assessment techniques are used and adequate education and follow-up are provided. The NHLBI Recommendations Regarding Public Screening for Measuring Blood Cholesterol have been widely distributed in the expectation that they will improve the quality of public screenings.

One of our primary goals in disease prevention is to facilitate appropriate and early application of current research advances related to heart, lung, and blood diseases and to transfusion medicine. The time between the development of advances in new knowledge and their successful transfer into medical practice and to the public has become remarkably short. Let me tell you about some recent activities that are of immediate benefit to the public health of the United States.

Whenever the Institute undertakes a clinical trial of a drug intervention, it does so with the expectation that the results will lead to improved approaches for management and prevention of disease. However, there are times when a clinical trial demonstrates findings that, while unanticipated, are as important as if the original premise of the study had been confirmed. The Cardiac Arrythmia Suppression Trial was designed to evaluate the effectiveness of three antiarrhythmic drugs in preventing sudden death in heart attack survivors with mild arrhythmias. Last April, use of two of the drugs was halted when it became apparent that death occurred almost twice as frequently among those who took the drugs as among those who took a placebo. Because these drugs had been widely prescribed in the United States for mild arrhythmias, these findings have had a widespread, immediate impact on physician practices. Considerable savings of lives and medical costs should result. This experience underscores the importance of the clinical trial as a research tool which, in this case, revealed that the drug, rather than the disease, was the cause of excess mortality.

Women account for about half of all deaths from CHD in the United States and are twice as likely as men to die in the first few weeks after a heart attack. Attention is now being focused on the mechanisms by which CHD develops and progresses in women. For example, the relative freedom from heart attack experienced by women before menopause has generated investigations of the possible protective effect of hormones produced by the ovaries. Recently, investigators reported that natural menopause tends to lower "good" cholesterol, high density lipoprotein, and raise "bad" cholesterol, low density lipoprotein, but estrogen replacement therapy seems to nullify that effect. The NHLBI's Postmenopausal Estrogen/Progestin Interventions (PEPI) trial is evaluating whether various combinations of estrogen and progestational agents reduce risk factors for heart disease. The results are expected to provide a solid basis for preventive treatment recommendations.

The Institute is also focusing a major effort on risk factor modification in selected populations. The Dietary Intervention Study in Children (DISC) is assessing the efficacy and safety of a cholesterol-lowering diet for prepubescent children who have high cholesterol levels. The NHLBI Growth and Health Study is developing important new information about obesity and its consequences in Black and white preteen and teenage girls. The Lung Health Study for early detection and prevention of chronic obstructive pulmonary disease is the first trial of risk factor modification in lung disease.

Considerable attention also is being directed toward a cluster of 11 southeastern states where the death rates from stroke are so high as to warrant the designation "stroke belt." Of particular interest and concern are the observations that, among Blacks in those states, hypertension is more prevalent, more severe, and less well-controlled, and obesity is more common than among Blacks in other regions. The National High Blood Pressure Education Program has developed a multifaceted stroke belt intervention strategy to address the particular problems associated with hypertension control in the Southeast.

This year has been one of great progress in basic and clinical investigations into the pathogenesis of cystic fibrosis (CF). Discovery of the CF gene has expanded opportunities for understanding the underlying biochemical defect and designing new therapies. Translation of these concepts into improved care for CF patients will require years of investigation. On the immediate horizon, however, is a promising therapy that inhibits excessive sodium and water absorption. Building on the basic science observation that a defect exists in sodium absorption in CF cells, a pilot study of aerosol-administered amiloride demonstrated its ability to thin out airway secretions and slow the disease-induced decline in pulmonary function. If confirmed in large clinical studies, these findings will represent an important contribution to modern CF therapy.

Over the years, I have reported a number of advances resulting from our research program in neonatal respiratory distress syndrome (RDS), and I am happy to report today that a major goal has been achieved. Ever since it was discovered that RDS is caused by a deficiency of surfactant, development of an effective, safe replacement therapy has been a dream of clinicians and basic researchers. In 1989, approval was given for wider use of two experimental surfactant preparations shown effective in improving the course of RDS through clinical studies sponsored by NHLBI. Successful treatment with surfactant replacement is expected to reduce the severity of RDS and need for mechanical ventilation. Long-term follow-up studies are under way to establish the impact of surfactant replacement on the incidence of such complications as bronchopulmonary dysplasia, a serious chronic lung condition that affects 8,000 American newborns each year.

The NHLBI has been a leader in the development of asthma self-management strategies effective in reduction of the frequency and severity of asthma attacks and emergency room visits. Results of our research programs are being widely disseminated through the National Asthma Education Program (NAEP), initiated in 1989 to provide patient, family, professional, and public education about asthma and its management. An NAEP Expert Panel on Management of Asthma has been convened to develop national guidelines for physicians who treat patients with asthma. Improved asthma management is needed particularly for Blacks, who are twice as likely as whites to be hospitalized for asthma and three times as likely to die of asthma. Although corresponding data for Hispanics are not available, a number of barriers to effective asthma management exist, such as low educational and literacy levels and lack of access to continuing health care. In response to this need, the Institute recently announced a new research program to develop interventions that address the special needs of Black and Hispanic children. With this coordinated approach, the Institute hopes to play a major role in the control of asthma by helping individuals learn to manage their chronic disease.

We are pleased to report progress in the quest for improved treatment of two hereditary blood disorders, sickle cell anemia and Cooley's anemia. Scientists have developed transgenic mice whose red blood cells make human hemoglobin. They are now able to implant sickle hemoglobin genes in these animals and cause production of the human hemoglobin S found in patients with sickle cell anemia. These developments bring us far closer to having animal models of this disease to facilitate detailed studies and enhanced exploration of experimental treatments. Researchers studying Cooley's anemia have reported success in the development of oral iron chelators, agents that remove the toxic iron accumulation associated with multiple blood transfusions. Several new agents have now been approved for experimental use and it is hoped that they will prove effective in the management of this chronic disease and eventually replace chelators that must be injected daily. During the past year, the size of the National Bone Marrow Registry, now operating under NHLBI management, doubled to include over 78,000 potential donors. Bone marrow transplantation has become an accepted and effective treatment for an increasing number of diseases of the bone marrow and immune system. Over 270 transplants have been performed as a result of the registry. It is anticipated that improved access to tissue-matched donors and better transplant technology will make bone marrow transplantation an acceptable alternative treatment for severe sickle cell anemia and other serious hematologic disorders.

The National Blood Resource Education Program (NBREP) was formally launched in October 1987 to ensure an adequate and safe blood supply and ensure appropriate transfusion of blood and blood components. In the past year, the program released two major reports providing guidance for health professionals --one on the use of red blood cells, platelets, and fresh frozen plasma and the other on the use of autologous blood. In addition, a mass media public education program was begun to supplement efforts of local blood centers in recruiting blood donors. This year an important program focus will be production of a resource kit for blood banking personnel to improve donor recruitment and retention.

Results of AIDS research have already improved the quality and length of life of patients and helped reduce the spread of the AIDS virus. Clinical researchers have focused much attention on the lung, the organ most affected as a result of HIV infection. NHLBI intramural scientists recently reported finding abnormally reduced levels of glutathione, a natural substance in the body necessary for immune function, in the lungs and blood of men infected with the AIDS virus. An aerosolized form of glutathione has been developed and is now being tested in humans to determine whether it can safely restore the deficiency in the lung. Since glutathione plays an important role in enabling the immune system to function normally, it is hoped that increasing the levels of glutathione will help to prevent AIDS-associated lung infections.

These accomplishments reflect the breadth and depth of our programs of basic and clinical research, clinical trials, and public and professional education. We report them with pride and with confidence that they will provide a foundation for many future improvements in the public health of the United States.

Mr. Chairman, the FY 1991 budget request for the National Heart, Lung, and Blood Institute favors basic research and totals $1,112,502,000. I would be pleased to answer any questions that the Committee may have.

BIOGRAPHY OF DR. CLAUDE LENFANT

October 12, 1928, Paris, France

Education: B.S., University of Rennes, France, 1948. M.D., University of Paris, France, 1956.

Professional History: 1957-1958, Research Fellow, University of Buffalo, New York. 1958-1959, Research Fellow, Columbia University, New York. 1959-1960, Assistant Professor of Physiology, University of Lille, France. 1961-1965, Clinical Instructor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1966-1967, Clinical Assistant Professor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1968-1971, Associate Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle. 1970-1972, Acting Associate Director, Collaborative R&D Program, National Heart and Lung Institute, NIH. 1970-1972, Associate Director for Lung Programs, National Heart and Lung Institute, NIH. 1971-1972, Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle. 1972-1980, Director, Division of Lung Diseases, National Heart, Lung, and Blood Institute, NIH. 1981-1982, Associate Director for International Research, NIH. 1981-1982, Director, Fogarty International Center for Advanced Study in the Health Sciences, NIH. 1982-Present, Director, National Heart, Lung, and Blood Institute, NIH.

Professional Organizations: Association of American Physicians, American Society for Clinical Investigation, American Physiological Society, American Federation for Clinical Research, French Physiological Society, International Federation for Medical Electronics, American Society of Zoologists, Society for Experimental Medicine and Biology, Undersea Medical Society, New York Academy of Science.

Honors, Awards: Thesis Prize, University of Paris, France, 1956. Commendation Tohoku Medical Society, Sendai, Japan, 1973. Superior Service Honor Award, DHHS, 1974. Regents' Professor, University of California, Los Angeles, 1975. Testimonial Dinner, American Thoracic Society, 1979. Honorary Fellow, American College of Chest Physicians, 1979. Honorary Professor, National Yang-Ming Medical College Taipei, Taiwan, 1980. Honorary Professor, Universidad Peruana Cayetano Heredia, Lima, Peru, 1981. Senior Executive Service Performance Award, 1982. Elected Institute of Medicine, National Academy of Sciences, 1983. American Heart Association Scientific Councils' "Distinguished Achievement Award," 1983. Senior Executive Service Performance Award, 1983. Honorary Fellow Council on Clinical Cardiology - American Heart Association, 1984. Senior Executive Service Performance Award, 1984. Forrest M. Bird Contributory Award, American Respiratory Therapy Foundation, 1985. Senior Executive Service Performance Award, 1985. Presidential Meritorious Executive Rank Award, 1987. Elected Honorary member, Royal Society of Medicine, England, 1988. Honorary Doctor of Science, State University of New York, Buffalo, 1988. Elected member USSR Academy of Medical Sciences, 1988. Cystic Fibrosis Foundation "Breath of Life" Award, 1988.

Authorship, Editorship: Author or Co-Author of 192 scientific publications Served on Editorial Boards of: Am. Journal of Physiology; Journal of Applied Physiology; Respiratory Physiology; Am. Review of Respiratory Disease; Undersea Biomedical Research; Proceedings of Society for Experimental Biology and Medicine; Revue Francaise des Maladies Respiratories; Journal of Applied Physiology; Respiration, Environmental and Exercise Physiology; Am. Journal of Medicine; Continuing Education for Family Physicians; Executive Editor of 40 volume monograph series, Lung Biology in Health and Disease.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

ARTIFICIAL HEART

Question. As you know, the Food and Drug Administration (FDA) withdrew its approval for use of the Jarvik Artificial Heart. Why do you believe the FDA made this decision?

Answer. It is our understanding that the FDA made this decision because they believe that the manufacturer, Symbion, 1) was not employing proper quality control measures in the manufacturing processes for the Jarvik Artificial Heart, 2) failed to promptly report adverse clinical events to the FDA, and 3) was not effectively discharging the proper monitoring responsibilities required of a "Sponsor" under the FDA investigational device exemption (IDE) regulations. The Jarvik-7 device is not a part of the National Heart, Lung, and Blood Institute (NHLBI) directed artificial heart program, although the enabling science and technology for the Jarvik-7 evolved from grants supported by the Institute (mostly at the University of Utah). FDA withdrawal of the Jarvik-7 should have little impact on the NHLBI program.

Question. Did the FDA consult your Institute before making this decision?

Answer. The FDA did not consult the NHLBI before making this decision.

Question. I understand that your Institute continues to pursue research on four different kinds of artificial hearts and that you are in the second year of a five year program. Last year, there was some discussion of discontinuing these artificial heart programs in favor of a left ventricle assist device. Where do we stand on progress, both with the artificial heart program and the left ventricle assist program?

Answer. Under the electrically powered implantable total artificial heart (ETAH) program, three systems for replacement of the natural heart and one system for bi-ventricular assistance are being developed. New innovations are being evaluated during the design phase. For example, one system employs a compliance chamber in the wall of the left atrium to provide for physiologically balancing the right and left sided cardiac outputs. Another concept employs a unique "platelet" manufacturing method that simplifies the fabrication of the energy converter. Each system has a reliability model and quality control is being considered at each design phase.

Prototype devices are being prepared for animal tests later this year. Because of advances in our understanding of the science and engineering of mechanical support devices, it has been possible to compress an effort that previously required ten or more years into the first three years of the current program. At the conclusion of this activity we expect to have systems that have the potential for five years of safe and effective operation in a clinical setting.

An electrically powered implantable ventricular assist system

(EVAS) has recently completed rigorous reliability tests demonstrating two years of continuous operation without a mechanical or electrical failure; similar versions of this device have successfully completed animal tests. There has also been a successful bridge-to-transplant experience (57 cases) in which the device has functioned with a wire tether for electrical energy transmission and control. These patients have been supported for up to six months until a donor heart becomes available.

We are planning a clinical assessment for the totally implantable version of the EVAS. An award has been made for production of the EVAS to be used for this assessment. This will be the first chronic implant of a device that uses electrical power transmitted transcutaneously. The only external component required will be electrochemical batteries. It is expected that two clinical centers will be selected to implant the devices, and carry out follow-up assessment of the patients and the device. Experimental implants of devices are scheduled to begin in the summer of 1991.

EDUCATION PROGRAMS

Question. Dr. Lenfant, you of course operate a number of education programs at an expense of approximately $6 million per year. The issues of these programs include high blood pressure, cholesterol, bone marrow and blood sources, asthma, and possibly a new heart attack early warning program. I would like to compliment you on your pursuit and support of these education programs, I believe it is incredibly important for us to put the results of all the research findings to work. It is always difficult to find what you spend on these programs as it is buried in your management contract line-item. Shouldn't we have a separate line-item for these education programs so that we can highlight them and help ensure they receive adequate funding each year?

Answer. The Institute has considered requesting a line item for its education programs, but has not done so because there are both advantages and disadvantages in having such a line. From a programmatic viewpoint, a line item does offer greater visibility and would ensure that these programs receive special attention when budget decisions are made. On the other hand, these programs are closely tied to our research programs, and a separate line may give the impression that these activities are severable from the research programs that have led to their development.

From an administrative standpoint, a separate line item would simplify the problem of showing and tracking the amount available for our education programs. Conversely, a separate line item would require separate controls over salary dollars and full time equivalent personnel that may restrict the Director's flexibility to deal with day-to-day operating problems.

The Institute, therefore, has not pushed for a line item for its education program, but would not oppose its establishment.

CENTERS PROGRAM

Question. What is the status of your Centers program?

Answer. Since 1971, the Institute has supported Specialized Centers of Research (SCORs) to advance basic knowledge and generate techniques and methods of clinical management and prevention in selected areas of heart, blood vessel, lung, and blood research. Currently, 54 centers are supported in 12 topic areas. Since 1972, the Institute has also supported at least 10 Comprehensive Sickle Cell Centers that combine basic and clinical research and clinical trials with application, training, and community service projects.

In regard to the funding status of research centers, the Institute is concerned about a decline in funding since FY 1987 from $87,424,027 to the FY 1991 estimate of $86,295,000. In 1987, the average cost of a center award was $1,457,000. In 1991, it is estimated to be $1,348,000. The funding status of our centers programs has reached a point where the Institute is considering a reduction in the number of centers supported.

Question. What research are they doing?

Answer. The Institute's Specialized Center of Research (SCOR) program supports research on related important topics where a concentration of research resources, facilities, and personnel permit a multidisciplinary approach to research problems. The centers provide a unique opportunity for basic and clinical scientists from a variety of disciplines to collaborate on research in a particular disease area. The NHLBI is an Institute with a focus on specific diseases, and a large measure of its success comes from the rapid translation of research findings to bedside medical practice. The centers program is critical to that effort, because it is the Institute's often exclusive avenue for clinical research in a given disease area. The SCOR program ensures that advances in basic sciences are translated rapidly into clinical application and that clinical needs provide direction for the basic sciences. Over the years, the research of the SCOR programs has contributed directly to the betterment of public health through new approaches to prevention, diagnosis, and treatment of disease.

The current SCOR program includes research on atherosclerosis, hypertension, ischemic heart disease, chronic diseases of the airways, respiratory disorders of neonates and children, pulmonary vascular diseases, occupational and immunologic lung diseases, adult respiratory failure, cardiopulmonary disorders during sleep, cystic fibrosis, thrombosis, and transfusion medicine.

The Comprehensive Sickle Cell Centers include components of basic, applied, or developmental research; clinical applications and trials of various modes of therapy; demonstration projects on methods or approaches to diagnosis, counseling, and education; and training of professional and allied health personnel in the specific problems of sickle cell disease. Through the years, these centers have contributed to a number of significant advances in the medicine of sickle cell disease.

Question. Do you expect that the Institute will need to continue its practice of downward negotiations with the Centers under the 1991 Budget Request?

Answer. Under the 1991 Budget Request, the Institute anticipates center awards will be 24-25 percent below the approved levels.

Question. Will this affect the quality of the research in the Centers?

Answer. The anticipated downward negotiations will undoubtedly affect the ability of the Institute's centers to carry out research at the planned level. A common result of budget reductions is to reduce the scope of the proposed research. Given the highly integrated design of the centers programs, any reduction in workscope can be expected to have a multiplying effect on all aspects of the program. Further, in the clinical research area, budget reductions may reduce the number of patients that can be studied as well as the number of control subjects. These effects would tend to slow the progress of research in the scientific area addressed by the program.

These reductions also hamper the ability of individual centers to collaborate with each other in the planning and execution of clinical, epidemiologic, or treatment studies that require a multicenter effort. Finally, diminished budgets would limit the capability to provide training environments in which young scientists, particularly physicians, may gain important research experience.

HEART ATTACK CARE

Question. Are we making progress in delivering speedy care to those who suffer heart attacks?

Answer. When a person suffers a heart attack "time is muscle," and the faster therapy can be administered, the less likely the patient is to suffer death, heart muscle impairment or dysfunction. While knowledge of new heart attack interventions, in particular thrombolytic therapy (clot-dissolving therapy) is spreading, there is room for improvement.

The National Heart, Lung, and Blood Institute (NHLBI) is currently considering an educational effort to reach key groups with relevant messages concerning identification and treatment of patients who have suffered a heart attack. The new educational effort has been tentatively titled the National Heart Attack Alert Program (NHAAP). A number of issues must be examined before launching a national education program, however. As a next step in the consideration process, NHLBI will conduct a symposium in October 1990 titled: "Rapid Identification and Treatment of Acute Myocardial Infarction: Issues and Answers." Proceedings will be published and disseminated within the professional community to raise awareness of the issues and to secure comment concerning educational efforts. The proceedings will be used by the NHLBI to weigh the advisability of establishing a program and in determining strategies to reach critical target audiences.

Question. What are you doing to inform health care professionals and the public about recent advances in treatment of heart attacks?

Answer. The goal of treatment in an acute myocardial infarction (heart attack) is to prevent death and disability by preserving as much heart muscle as possible. In order to achieve this goal, it is essential to minimize the time from the first symptoms and signs to treatment action. There are three critical phases in treating heart attacks: (1) recognition of the symptoms and signs requiring action by the victim and those in his/her environment, (2) action prior to arrival at the hospital or emergency center, and (3) action upon arrival at the hospital or emergency center. Recent advances in therapy, especially from clinical trials evaluating thrombolytic therapy (clot-dissolving therapy), suggest that impressive reductions in morbidity and mortality in heart attack patients are associated with the use of such therapy.

The National Heart, Lung, and Blood Institute (NHLBI) is currently considering an educational effort to reach key groups with relevant messages concerning identification and treatment of patients with heart attacks. The new educational effort has been tentatively titled the National Heart Attack Alert Program (NHAAP). The program would have as its goal the reduction of morbidity and mortality associated with heart attacks through the rapid identification and treatment of those with symptoms and signs of a heart attack. The implementation of the proposed program will be discussed in greater detail at a symposium that is planned for the near future. At that time, a funding plan and a time schedule will be determined for the NHAAP.

ARTERIOSCLEROSIS

Question. Can the artery lesions (arteriosclerosis) that cause heart attacks regress?

Answer. Evidence is accumulating that it may be possible to reverse the fatty deposits that constitute arteriosclerosis. Data from two x-ray studies of the coronary arteries of persons treated with cholesterol altering therapy have recently been reported. The Cholesterol Lowering Atherosclerosis Study (CLAS) and the Familial Atherosclerosis Treatment Study (FATS) were double-blind, placebo-controlled clinical trials involving persons with very advanced coronary artery disease. Treatment produced very marked reductions in low density lipoproteins ("bad" cholesterol) and marked increases in high density lipoproteins ("good" cholesterol). In both studies, there was a slow-down of the progression of the fatty lesions in the coronary arteries of the treated group as compared with the control group. In a significant number of treated cases there was also clear evidence of improvement in artery status, which presumably reflected regression of the deposits.

Another study, reported quite recently, demonstrated the effect of diet and lifestyle changes on atherosclerotic lesions. The subjects adopted a very low-fat diet that excluded poultry, red meat, oils and fats, fish and all but small amounts of nonfat dairy products. In addition, they were required to give up smoking, exercise moderately three times a week, and engage in daily sessions of stress management that included relaxation therapy. At the end of a year, 82 percent of these subjects had artery changes indicating that the buildup of fatty deposits was reversing.

ARTIFICIAL HEART

Question. What is the current status of the artificial heart program?

Answer. The Institute's circulatory assist program, of which the total artificial heart is a part, consists of projects from the most fundamental levels of the molecular structure and function of implanted biomaterials, or organ physiology following device implant, to the development of advanced pediatric and adult circulatory support devices.

Currently, the circulatory assist program supports 31 investigator-initiated grants and six research and development contracts. Grant-supported activities include: 1) cardiac assist devices energized by skeletal muscle, 2) down-sized specialized systems for pediatric use and 3) immunoresponses following blood pump implant.

Contract activities include development of the total artificial heart, reliability testing of ventricular assist systems and a new program designed to assess an electrically powered totally implantable ventricular assist system in patients called EVAS. EVAS has recently completed rigorous reliability tests demonstrating two years of continuous operation without a mechanical or electrical failure. An award has been made for the production of EVAS and when it reaches the clinical testing stage it will be the first chronic implant of a device that uses electrical power transmitted transcutaneously. Experimental implants of these devices are scheduled to begin in the summer of 1991.

Under the electrically powered implantable total artificial heart (ETAH) program, three systems for replacement of the natural heart and one system for bi-ventricular assistance are being developed. In January, 1990, the program is in the third year of a planned 5-year development cycle. Prototype devices are being prepared for animal tests later this year. At the conclusion of this activity we expect to have systems that have the potential for five years of safe and effective operation in a clinical setting.

Other basic technology and science for the circulatory assist program is being provided through 51 investigator-initiated grants. The program emphasizes studies of the initial events following implant, surface-active methods to retard thrombosis, mechanisms of arterial graft failure, vascular healing, calcification, and tissue hyperplasia following implant.

EDUCATION PROGRAMS

Question. How do your education programs this year differ from last year's education efforts?

Answer. Two new efforts include the first program activities of the new National Asthma Education Program (NAEP), begun in March 1989, and analyzing the feasibility of a National Heart Attack Alert Program (NHAAP). The NAEP, begun in recognition of the growing prevalence of the condition and increasing mortality, is aimed at developing broad programs of professional and patient education, especially efforts aimed at minority groups. In 1990 the report of an expert panel will provide, for the first time, recommendations on comprehensive asthma diagnosis and treatment. In 1990 NHLBI will also conduct a needs assessment and planning effort for a program on early warning signs of heart attack. The effort would focus on the life-saving potential of reducing damage to the heart by decreasing the time interval between the onset of heart attack and admission to an intensive care setting.

For the first time this year the National Heart, Lung, and Blood Institute's (NHLBI) education efforts are based on a set of "core initiatives" developed to help prioritize educational needs and opportunities and make efficient use of existing resources. Each national education program has its own set of core initiatives. The initiatives focus on a variety of program strategies, including: improving the management of cardiovascular disease risk factors through professional and patient education; promoting public awareness and behavior change in areas such as dietary change to reduce blood cholesterol and increasing blood donation; enhancing program efforts to reach under-served and minority populations; and strengthening the role of the voluntary and professional organizations who are partners in NHLBI's education programs. The core initiatives provide for continuity in program development, as well as the addition of new approaches and products.

Question. Were you able to reprogram more funds for the education program this year?

Answer. Due to the importance of several recently recognized needs related to our educational activities, the Institute has submitted a request to reprogram funds into this area. Because our educational activities have been designated a "Program, Project or Activity", the House and Senate Appropriation Committees will need to approve this reprogramming action.

Question. What is the current funding level of your education and prevention program?

Answer. The 1990 estimated level of funding for NHLBI's education and prevention programs is $5,736,000 before reprogramming.

Question. What types of new cholesterol awareness education programs do you have in place?

Answer. The National Cholesterol Education Program (NCEP) is directing educational messages to both professional and public audiences. The major emphasis of the educational effort thus far has been on encouraging the detection and treatment of high-risk adults. The public has been urged to have their cholesterol level checked and, if it is high, to lower it using physician-supervised dietary therapy as the primary treatment. Guidelines for the treatment of high blood cholesterol have been distributed to physicians, together with patient education brochures and fact sheets. This past year, the NCEP has developed a dietitian's kit and a cholesterol education program for nurses to promote greater involvement of these two professional disciplines in treating the high-risk patient.

A new thrust of the NCEP is the population approach. The report of an expert panel released on February 27 recommends that the American public in general, and not just high-risk individuals, lower their blood cholesterol levels by adopting a low-saturated fatty acid, low-fat, and low-cholesterol eating pattern. Messages encouraging the public to eat in this heart-healthy way will be incorporated into the NCEP's radio and television public service announcements and into the educational efforts of the 38 organizations on the program's Coordinating Committee. In addition, the NCEP is trying to promote higher quality in public cholesterol screenings by distributing guidelines for such screenings, developing criteria for training, and encouraging greater involvement by State health department personnel in this area.

The Institute is constantly re-examining the science base to insure that the foundation for our education programs is the best available scientific evidence. Recently, three issues have been the subject of scrutiny within the NHLBI and the Coordinating Committee of the National Cholesterol Education Program, and have also been the focus of attention in the recent public debate about cholesterol and coronary heart disease. Therefore, the Institute plans to hold workshops in order to re-examine the latest scientific data in these three areas and take appropriate action. The first issue is whether elevated blood cholesterol is a risk factor for coronary heart disease in women and the elderly. The Framingham Heart Study and other data have been cited on both sides of this issue, and the workshop will analyze the currently available epidemiological and clinical trial data. The second issue is whether there is a risk of lowering blood cholesterol too much. As with blood pressure, the curve of total mortality versus serum cholesterol is J-shaped; that is, the lowest cholesterol levels are associated with somewhat higher mortality rates than slightly higher cholesterol levels. The third issue addresses the potential health and cost impact of various cholesterol-lowering strategies on individuals and society. This workshop will address the extent and distribution of cardiovascular diseases in the United States and other industrialized countries; the degree of reduction in cholesterol levels and in adverse health outcomes possible by available intervention strategies; the identification or development of health/economic models with appropriate outcome measures; and a comparison of the cost and effectiveness of cholesterol-lowering interventions with that of other expenditures in the health prevention area.

Question. Have you seen or been able to detect a change in the incidence of cardiovascular diseases as a result of your education efforts?

Answer. The data for drawing firm conclusions about the incidence of cardiovascular diseases (CVD) is simply not available, but we do know that mortality from CVD has been dropping for the past 20 years. This decline is due in part to better control of the risk factors; levels of blood cholesterol, blood pressure, and smoking have all declined. Since the National Cholesterol

Education Program was launched in 1985, the attitudes and behaviors of professionals and the public have changed. For example, the percent of the public who have had their cholesterol checked has risen from 35 percent in 1983 to 66 percent in 1989. We anticipate that these changes in professional and public actions will lead to lower blood cholesterol levels and, in turn, to lower rates of coronary heart disease.

There are also clear associations between the National High Blood Pressure Education Program's (NHBPEP) educational efforts and improvements in the public's knowledge about the value of controlling blood pressure, the public's improved behavior to seek medical care for this disease, their ability to control hypertension, and a reduction in age-adjusted stroke mortality. Prior to the advent of the NHBPEP, 24 percent of the adult population knew of the relationship between high blood pressure and stroke and high blood pressure and heart disease. Today, more than three-fourths of the population know of the relationship between hypertension and these other diseases. Every six months, approximately three-fourths of the population have their blood pressure measured, and control rates for this important public health problem have nearly tripled. We believe these changes have contributed to the remarkable fact that age-adjusted stroke mortality has declined by nearly 54 percent since the NHBPEP's inception.

Question. What role can we in Congress play in this education and behavior modification program?

Answer. The Congress has already played a major role in our education efforts by highlighting these programs in authorizing legislation, appropriation committee report language, and by distributing information to constituents. The Joint Resolutions on High Blood Pressure Awareness Week and Know Your Cholesterol Week were especially helpful to our community outreach efforts in these areas. The Congress, together with the Administration, has also helped by supporting the basic research that undergirds these educational efforts, by maintaining a balanced set of programs within the Institute, and by recognizing the close connection between the research programs of the Institute and opportunity to expeditiously disseminate the results of this research effort.

PROGRAMS OF EXCELLENCE IN MOLECULAR BIOLOGY

Question. The Programs of Excellence in Molecular Biology were created to promote interdisciplinary investigations in molecular biology research including basic research in the heart, blood and lung systems, and to strengthen the field by training new investigators. Could you tell us about how many investigators are involved in this program?

Answer. All together, there are eighty investigators (M.D. or Ph.D.) involved in the three NHLBI Programs of Excellence in Molecular Biology.

Question. How many of these investigators are new?

Answer. Of these eighty investigators, 11 are senior level molecular biologists new to cardiovascular, pulmonary, and blood research, six are senior level investigators new to molecular biology, and 52 are young investigators new to the application of molecular biological approaches to cardiovascular, pulmonary, and blood research problems.

Question. What is the extent of funding for this program?

Answer. Currently, the NHLBI spends approximately 6.8 million dollars on these three Programs of Excellence in Molecular Biology. They are located at the University of Cincinnati, the Massachusetts Institute of Technology, and the University of California at San Francisco.

CYSTIC FIBROSIS

Question. What does the identification of the gene for cystic fibrosis mean for patients who suffer from this disease, and how does the Institute plan to capitalize on this important new discovery?

Answer. The discovery of the cystic fibrosis (CF) gene offers hope to those suffering from this devastating disease as it provides pulmonary scientists with a powerful new tool for understanding the basic defect underlying this disease and its eventual cure.

To capitalize on this important new discovery, scientists supported by the NHLBI are already beginning to determine the physiologic function perturbed by the CF gene product and its localization. One important goal is to see if insertion of the normal version of the gene into CF cells will correct their dysfunction. Studies are underway to lay the foundation for delivering normal genes into CF cells to correct the CF defect. Another goal of these studies is to establish how the CF gene product relates to the ion transport abnormality characteristic of CF epithelia, and to understand the link between the defective ion movement, the thickened mucus, and the propensity to airway infection.

Investigators are now trying to develop animal models of CF, which are important for not only studying the pathophysiology of this disease, but also for developing new and more effective therapies. Animal models would enable analyses of the disease process under conditions in which multi-systemic interactions remain intact and validation of findings with in vitro model systems such as immortalized (i.e., indefinite life-span) CF cells, recently developed by NHLBI-supported investigators. Additionally, the availability of an animal model would permit clinical testing of potential pharmacologic and genetic approaches to the therapy of CF.

The availability of probes for the CF gene is already promoting investigations into alternative mutations that may serve to explain the clinical heterogeneity of CF, that is, why some CF patients have lung and pancreatic problems while others only have respiratory involvement and why some have milder forms of the disease while others are more severely afflicted. Knowledge of which mutations correlate with which forms of disease could be very useful for diagnosis and treatment.

The remarkable discovery of the CF gene is accelerating progress in efforts to understand and treat this disease and is improving prospects for a brighter future for those suffering from this fatal genetic illness.

ASTHMA

Question. What is your National Asthma Education Program doing to halt the increasing incidence and death rates of asthma in the United States?

Answer. Asthma is a serious chronic condition, affecting approximately 10 million Americans. People with asthma experience well over 100 million days of restricted activity annually and costs for asthma care exceed $4 billion a year. There are several disturbing trends evident in the national statistics on asthma. Both mortality and prevalence are on the increase along with the number of individuals hospitalized for this chronic condition. In an effort to improve the early detection, treatment and management of asthma, the National Heart, Lung, and Blood Institute (NHLBI) launched a National Asthma Education Program (NAEP) in 1989. Over 20 professional, voluntary, government and lay organizations are represented on a coordinating committee to help plan program objectives, set target goals and disseminate information about asthma. The NAEP is modeled on the successful National High Blood Pressure Education Program and the National Cholesterol Education Program.

The first major task of the NAEP is to develop a report on Management of Asthma to provide guidelines for health professionals on diagnosis and treatment. Planned for completion in December 1990, the report will also include information on the roles of exercise and allergy in asthma, and asthma in special populations such as the elderly and pregnant women. This report will be distributed widely to primary care physicians in a "Physician's Kit" which will also contain booklets on Teaching Your Patients About Asthma, and Managing Your Asthma (for asthma patients). Since over one-third of the people with asthma are children, the NHLBI is working with the Department of Education to explore collaborative efforts to develop asthma education activities and programs for the schools which target teachers, nurses, coaches and school administrators. The School Asthma Education Subcommittee of the National Asthma Education Program met recently and recommended several activities to carry out with the Department of Education. These include the development of a Directory of Asthma Resources for schools; the development of pamphlets targeting a broad range of personnel within the school environment; the development of asthma inservice training courses for schools; and the establishment of a network of groups to promote better management and control of asthma in schools. The potential outcome would be reduced absenteeism, better recognition that asthma is a serious disease that requires proper management, and increased participation in school activities by children with asthma. The NHLBI is confident that these coordinated efforts will make a major impact on both morbidity and mortality of asthma in children and adults in the United States.

ANIMAL RESEARCH

Question. In light of the continuing protests against the use of animals in biomedical research, can you cite specific examples of how animal research has contributed to improvements in care of patients with respiratory disease?

Answer. Respiratory distress syndrome (RDS), a life-threatening disease, strikes some 40,000 babies each year in the United States. RDS occurs when the infant's immature lungs fail to produce pulmonary surfactant, a substance that normally lines the lungs and prevents them from collapsing. Over the past 30 years, research has yielded promising ways to prevent or reverse lung damage in newborns with immature lungs. These treatments could not have been developed without the use of animal models of the disease--including rabbits, lambs, rats, hamsters, ferrets, and more recently baboons. For example, experimental efforts to replace the missing surfactant have relied on animal models, both as a source of surfactant and as a model for testing safety and effectiveness. Surfactant isolated from the lungs of cows and pigs was tested on animals and surfactant from cows is now being used to treat human infants with RDS; animals also are used to test a recombinant surfactant for safety and effectiveness. Prematurely born baboons with RDS are allowing NHLBI grantees to test different methods of delivering mechanical ventilation in an attempt to find the least damaging means of getting oxygen into the bloodstream. The infant baboons also are used to test corticosteroids, antibiotics, and other drugs for treating and minimizing the lung damage that can result from the ventilation of surfactant deficient, infection prone premature lungs. Today, many prematurely born infants owe their lives to RDS treatments that would not have been possible without the use of animals in research.

BONE MARROW REGISTRY

Question. Dr. Lenfant, in the FY 1990 report, the Committee urged you to continue efforts to fully develop the bone marrow registry. I understand that you have 95,000 people in the registry at this time. What are your goals for the number of people in the registry.

Answer. The tentative goal for the registry is 250,000 potential donors in the United States and 1,000,000 worldwide.

Question. Would this number provide adequate coverage?

Answer. The goal of 250,000 must be regarded as preliminary and subject to change as we gain knowledge about the frequency of various HLA type combinations in different population groups. However, it is important to recognize that it will not be possible to find a match for every patient no matter how large the registry. Some patients will have rare HLA combinations that are unlikely to be matched regardless of the size of the registry. The reason for having as many potential donors as possible in the registry is to minimize the number of emergency situations created by the needs of individual patients.

HEART AND LUNG DISEASES IN THE BLACK POPULATION

Question. Over the last year, many articles have been written about the continued increase in risk factors for heart and lung diseases in the black population. What efforts are being pursued by your Institute to reduce these risk factors?

Answer. The National Heart, Lung, and Blood Institute (NHLBI) recognizes the critical need to reduce the prevalence of risk factors for heart and lung diseases in the black population and has placed a special emphasis on developing and implementing programs to do so. Through the long-standing Evans County Study and other epidemiological studies supported by the NHLBI, data on differences in risk factors for heart disease and hypertension in blacks have emerged. Through the years, the Institute has initiated a number of programs to identify and develop improved methods to reduce risk factors for heart and lung diseases among black Americans. In the area of heart disease, the Institute supports programs that include: the investigation of the efficacy of both pharmacologic and nonpharmacologic treatments for sustained isolated systolic hypertension and mildly elevated diastolic hypertension in populations ranging in age from young adults through middle age to the elderly; the examination of the interaction between physiologic and behavioral factors in an attempt to explain the high prevalence of hypertension among blacks compared with whites; and the identification of factors that influence the health care seeking behavior of blacks with suspected or existing heart disease. The Institute recently implemented a program to identify and develop smoking cessation strategies that address the particular needs of minorities since smoking remains a major preventable cause of heart and lung diseases among blacks. In the area of lung disease, the Institute is testing, in low-income urban families with preschool children who have asthma severe enough to require hospitalization, the effectiveness of health education in improving the management of asthma. Plans are under way to support a new program this year to develop approaches that will reduce morbidity among black and Hispanic children with asthma. These efforts will improve health behavior and thereby improve the quality of life for asthmatics.

The rapid and effective dissemination of research findings on risk factors for heart and lung diseases and how to reduce them is essential for blacks and other minorities. Through its education programs, the NHLBI applies numerous strategies to provide risk reduction information to the black community. Examples include minority-specific materials for use in community outreach activities, information kits that contain literature on risk factors and community approaches, and mass media campaigns. The most recent NHLBI media activity, "Strike Out Strokes (SOS)," addresses the high prevalence of hypertension and stroke in the southeastern United States and promotes increased awareness of hypertension and the importance of staying on therapy. The NHLBI Ad Hoc Committee on Minority Populations, a 15-member multi-ethnic group advisory to the Director, NHLBI, serves as an important source of information to the black community.

Question. Who in the Federal Government should take more responsibility in this area?

Answer. It is clear that the Department of Health and Human Services (DHHS) has made the reduction in risks for heart disease and other ailments for minority populations a top priority. Under Secretary Sullivan, the DHHS has stepped forward to take a leadership role in the search for effective solutions to this marked difference in mortality rates. In the Secretary's testimony to the House of Representative's Appropriation hearing for the DHHS 1991 budget the Secretary states "death rates among minorities for heart disease, cancer, stroke, AIDS and other disorders are far greater than those of the population as a whole. Correcting the disparity in health status between minority and non-minority populations remains one of my highest priorities." In order to achieve this goal the Secretary has asked the Department, and the Public Health Service (PHS) in particular, to focus on this critical problem.

It is important that all components of the PHS with responsibilities related to heart and lung diseases work together to ensure a reduction in risk factors for these diseases in the black population. Through its Year 2000 Health Objectives for the Nation, the PHS has established a framework within which the particular health needs of blacks, who experience higher rates of death at all ages and lower life expectancies, can be addressed. The programs of the National Heart, Lung, and Blood Institute constitute a major part of the PHS efforts to attain the Year 2000 goals established for blacks in the areas of high blood pressure control, smoking and health, and nutrition.

SICKLE CELL ANEMIA

Question. Are there any new breakthroughs in the area of sickle cell anemia?

Answer. Significant progress has been made in sickle cell research that has the potential for advancing the treatment of patients with sickle cell disease. A major development is the construction of laboratory mice with red blood cells that contain human sickle hemoglobin. Scientists inserted DNA molecules that contain the human alpha and beta globin genes into fertilized mouse eggs and a transgenic mouse line was established that synthesizes human sickle hemoglobin. When erythrocytes from these mice were deoxygenated, greater than 90 percent of the cells displayed the same characteristic sickled shapes as erythrocytes from humans with sickle cell disease. This exciting development opens new avenues for research on sickle cell anemia and such an animal model should enable scientists to study the disorder in greater detail, to evaluate current therapy and to try experimental treatments that presently are not feasible in human patients.

The clinical course of patients with sickle cell disease is extremely variable, ranging from mild to very severe symptoms. The ability to classify and predict clinical severity is essential for determining patient selection for various therapies, e.g., bone marrow transplantation, and for optimum health care planning. The Institute is seeking to develop a clinical severity index to use in making treatment decisions based on an analysis of clinical and genetic data on patients followed over the past ten years in the Clinical Course of Sickle Cell Disease project.

It has been known for some time that increased levels of fetal hemoglobin improve the clinical symptomatology in patients with sickle cell disease. Researchers have successfully demonstrated that hydroxyurea can safely increase fetal hemoglobin production. Preliminary findings are extremely encouraging and reports indicate that patients treated with this approach had increased hemoglobin levels and fewer clinical events, e.g., crises. A clinical trial to determine if the treatment with orally administered hydroxyurea, in maximal non-toxic doses, can decrease vaso-occlusive (painful) crises in patients with sickle cell disease by at least fifty percent is planned for the near future. If this clinical trial shows that the efficacy of hydroxyurea is 50 percent in reducing the number of crises in sickle cell patients this indeed will be a new "breakthrough" in the area of sickle cell anemia. This study should further our understanding about sickle cell disease and hopefully lead to improved therapy.

STROKE PREVALENCE IN SOUTHEASTERN UNITED STATES

Question. How do you account for the high numbers of stroke victims among blacks in the southeastern United States, and what can be done about this situation?

Answer. The exact mechanism whereby stroke deaths in the Southeast occur at a higher rate than in other parts of the country has not been determined. Further studies are needed to elucidate the complex etiology for the high rates of stroke mortality in this region. The available evidence is sufficient to warrant initiation of intervention programs in the Southeast, the so-called stroke belt, and to focus particular attention on the black population. The Institute is developing an outreach program to churches and to provide them with educational materials to help develop hypertension control programs at the church site. This activity will help raise awareness regarding blood pressure. A mass media campaign will be launched, titled, "Strike Out Strokes,(SOS)" designed to have major media markets in the Southeast United States promote the notion of increasing awareness for hypertension, as well as helping hypertensive patients stay on therapy. Interagency agreements will be developed with State Health Departments to fund innovative and demonstration projects designed to control blood pressure. Data from research studies has been analyzed and provided into a "fact sheet" for state hypertension control programs who use this information to design their own activities and measure progress. Regional conferences focusing on the management of hypertension will continue to be supported so that the latest results of clinical trials are brought to practicing clinicians. All of these efforts are designed to raise public and patient education efforts to support innovative ideas and demonstration projects to control this important public health problem.

HEPATITIS NON-A,NON-B

Question. When will we have an effective test to detect the presence among blood donors of the newly-discovered virus that causes non-A,non-B hepatitis?

Answer. Early in 1989, scientists at Chiron Corporation identified a major component of the agent responsible for causing non-A,non-B hepatitis which is now termed hepatitis C virus. Subsequently, a test was developed to detect antibody to this agent in human blood. Ortho Diagnostics Systems Corporation has teamed with Chiron Corporation to produce and market the donor screening test. Currently, the Food and Drug Administration is evaluating data from clinical studies of the test for licensure. It is anticipated that the test will be licensed and made available for routine donor screening within the next 4-6 months.

NATIONAL MARROW DONOR PROGRAM

Question. What can be done to help individuals with diseases such as leukemia, which are curable by bone marrow transplantation, to find suitable donors?

Answer. Finding an unrelated donor for a patient needing a bone marrow transplant depends upon how common or rare that patient's tissue (HLA) type is, upon how many donors are listed in the file, and upon statistical chance. Some HLA type combinations are so rare as to make it highly unlikely that a match will be found, no matter how large the file. Others are so common that many matches are readily available. Many HLA combinations are more common in some racial-ethnic groups than in others, and a few are characteristic of one population group. Most, however, are present in all racial-ethnic groups.

Generally speaking, the larger the file, the more likely a match will be found. The current National Marrow Donor Program goal is to list 250,000 Americans of diverse ethnic backgrounds in the Registry. As knowledge of the frequency of various HLA combinations in all parts of the American public increases, this goal will be adjusted, probably upward. Minority participation is planned to approximate their proportion of the general population, but this may need revision as information about their frequency of HLA combinations becomes available.

More than 70 percent of the donors now in the file are typed only for the HLA A and B antigens. The HLA-DR antigen is believed to be at least as important as the others for bone marrow transplantation. Currently, after an A and B match is found, the prospective donors are called in for DR typing. It would shorten the search process, decrease patient costs, and reduce total program costs if DR typing were done on all donors, as well as HLA A and B typing. Initial costs, of course, would increase. Shortening the search process and reducing patient costs would greatly help patients in need of a transplant. For some patients, the leukemia progresses during the search to the point where a transplant is no longer appropriate treatment. With a shortened search time, they could get their transplants and a chance toward a disease cure.

GENE TRANSFER

Question. I understand that the first experiments involving gene transfer in humans were carried out this year. What is the status of those experiments, and what is planned for the future?

Answer. The first protocol approved by the National Institutes of Health and the Food and Drug Administration for gene transfer experiments in human patients was carried out jointly by scientists in the intramural divisions of the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute. In these experiments, tumor infiltrating lymphocytes (TIL cells) that were removed from patients with advanced malignant melanoma, grown in tissue culture, transfected with a marker gene carrying resistance to the antibiotic neomycin, and then re-administered to the patient. The experiment had two principal purposes: (1) to determine whether there were any unknown hazards in administering transfected cells to humans, and (2) to follow the fate of the marked cells to obtain information that might lead to improved procedures in using TIL cells to treat malignant melanoma.

The first group of five patients was treated from May to July of 1989. All of the safety data were appropriately negative. There were no differences between the patients who received the marked TIL cells and those who have received unmarked TIL cells. Thus, the first major goal of the experimental protocol was successfully accomplished. Moreover, a very interesting result was obtained that has suggested a totally different way of performing TIL cell therapy for malignant disease. This new protocol is now being tested in a sixth patient, and a request has been submitted to extend the study beyond the 10 patients initially approved. In addition, another protocol has been submitted for gene transfer studies in patients with severe combined immune deficiency disease (SCID) which results from the genetic absence of the enzyme adenosine deaminase. The NHLBI Intramural Program plans to develop a bone marrow transplantation facility that will enhance our capability to conduct gene transfer research with human patients.

DIETS FOR CHILDREN

Question. Do you recommend the promotion of low-fat, low-cholesterol diet for American children as a way of preventing heart disease later in life?

Answer. The National Cholesterol Education Program's (NCEP) Population Panel recently released dietary recommendations for healthy Americans, including children. To reduce blood cholesterol levels in the general population, the Panel recommended reducing the amount of total fat in the diet to about 30 percent of calories, decreasing the amount of saturated fatty acids to less than 10 percent of calories and cholesterol intake to less than 300 mg. per day. The recommendations for children were developed after reviewing available evidence concerning benefits and safety for children and adolescents of this eating pattern that is lower in saturated fatty acids, total fat, and cholesterol than the usual American diet. It is recommended that healthy children follow this eating pattern as they begin to eat with the family, usually at two years of age or older.

Infants and children under the age of two years have dietary requirements different from those of older people. Infants whose diet is primarily mother's milk or formula often appropriately consume 40 percent or more of calories from fat. The Population Panel recommends that this well-established pattern of infant nutrition be encouraged.

The panel recognizes that caloric and nutrient needs of children are critical for supporting growth and development. Care must be taken to ensure to meet these needs of the growing child. Since eating habits developed during childhood can influence lifetime practices, the Panel urges prudent movement to the recommended eating pattern.

A forthcoming report from the Expert Panel on Blood Cholesterol Levels in Children and Adolescents will provide additional details about implementation of strategies for encouraging desirable eating patterns for healthy children. It will also provide guidelines for the detection, evaluation, and treatment of adolescents with high blood cholesterol levels.

In addition, the Institute is funding a study designed to look at the safety of a diet low in total fat, saturated fatty acids and cholesterol in growing children with high blood cholesterol levels. The diet used in the study is more restricted in total fat, saturated fatty acids and cholesterol than the diet recommended for healthy children, since the study addresses children with elevated low-density lipoprotein (LDL) cholesterol levels. These children will be followed for a minimum of three years with measurements of cholesterol response, growth, development, and cognition.

CHOLESTEROL EDUCATION

Question. In light of the recent controversy in the media regarding the benefits of lowering cholesterol, what direction is the National Cholesterol Education Program now taking?

Answer. NHLBI has made it clear in a variety of public statements, including a "white paper" developed jointly with the American Heart Association, that the scientific basis underlying the National Cholesterol Education Program (NCEP) is strong and compelling. There is an international science consensus that high blood cholesterol is a cause of coronary heart disease (CHD) and that lowering elevated levels of blood cholesterol reduces the risk of heart attacks. The strength of the science base has convinced over 35 national health-related voluntary and professional organizations to join the National Heart, Lung, and Blood Institute (NHLBI) in carrying out professional and public education through the NCEP. Since its inception in 1985, the NCEP has focused on a high-risk strategy: promoting the identification and treatment of individuals whose elevated blood cholesterol levels place them at high risk of CHD. Treatment guidelines for physicians, patient education materials, a mass media "Know Your Cholesterol" campaign for the public, recommendations for improving laboratory performance, and guidelines for public cholesterol screening have all been part of this effort.

In the coming year, the NCEP will encompass a population strategy. The basis for this approach was provided by an expert panel report which was released on February 27, 1990. This report provided recommended eating patterns for healthy Americans to lower blood cholesterol levels. At the same time that we are moving in this new direction, we are continuing to expand and review the science base to ensure that the foundation for our public health education programs is the best available scientific evidence. NHLBI is planning workshops to review current knowledge in three areas that have been the focus of attention both within the Institute as well as the public debate about cholesterol and coronary heart disease. (1) Is elevated blood cholesterol a risk factor for CHD in women and the elderly? Framingham and other data have been cited on both sides of this issue, and the workshop will analyze the currently available epidemiological and trial data. (2) Are there any risks from too low a blood cholesterol? As with blood pressure, the curve of total mortality vs. serum cholesterol is J-shaped; i.e., the lowest cholesterol levels are associated with somewhat higher mortality rates than slightly higher cholesterol levels. Previous examinations of the data have suggested that there is no basis to be concerned that high cholesterol levels might be lowered "too far." (3) What are the costs and health implications of cholesterol intervention? This workshop will address the extent and distribution of cardiovascular diseases in the United States and other industrialized countries; the degree of reduction in cholesterol levels and in adverse health outcomes possible by available intervention strategies; the identification or development of health/economic models with appropriate outcome measures; and a comparison of the cost and effectiveness of cholesterol-lowering interventions with that of other expenditures in the health prevention area.

ESTROGEN AND HEART ATTACK RISK

Question. Should postmenopausal women take supplemental hormones, such as estrogen, to reduce the risk of heart attack?

Answer. There is no question that heart disease is an important cause of death in older women. From the age of approximately 55 years and on, heart disease is the number one cause of death in women. Although much evidence points to a protective effect of estrogens, we still have insufficient information to make a blanket recommendation that postmenopausal women should take estrogen replacement therapy to reduce cardiovascular risk. The clinical trial, Postmenopausal Estrogen/Progestin Interventions (PEPI), co-funded by NHLBI and four other Institutes at the NIH, is designed to provide data which will assist us in answering this and related questions.

Recruitment for PEPI began in late 1989. A total of 840 women will be randomized into one of five treatment groups and followed for three years. At the end of the study period, the effects of treatment assignment on four primary endpoints will be evaluated: HDL cholesterol, systolic blood pressure, fibrinogen and insulin. PEPI will also evaluate treatment effects on secondary endpoints including lipids, lipoproteins and apolipoproteins, bone mass, selected hemostatic factors, endometrial changes, breast changes, quality of life assessments, and renin levels. The ultimate objective of PEPI is to provide information to assist physicians in making recommendations to their menopausal patients concerning estrogen replacement therapy.

A number of researchers believe the increased rates of heart disease in older women are in association with the menopause and the subsequent reduction of HDL-cholesterol levels attributable to decreasing estrogen production. Women who receive estrogen replacement maintain HDL-cholesterol levels similar to their premenopausal years. In many studies women who have used estrogen replacement therapy have substantially lower rates of heart disease and heart disease mortality than women who have not received replacement therapy. Much of this data, however is derived from women who received estrogen replacement therapy in the mid-1970's or earlier, when the estrogen dose tended to be about twice (or more) the amount currently used. Additionally, during that time period, progestational agents were not often used in conjunction with estrogen replacement. Current prescribing practices include lower doses of estrogen, and often include the addition of a progestational agent for certain groups.

Whether the reported benefits of estrogen replacement are dependent on dose is uncertain. Different progestational agents also have differential effects on estrogen. Possible effects of the manner in which the estrogen or progestational agent are administered have not been adequately evaluated. There is also insufficient information as to how long estrogen replacement therapy should be administered to achieve maximal benefit. It is anticipated that the PEPI trial will provide valuable information to help answer some of these questions.

COOLEY'S ANEMIA

Question. I understand that your institute is interested in the development of oral drugs to assist in the treatment of Cooley's anemia. Can you describe what your institute is doing now, and can do, in the development of this and other therapies relating to Cooley's anemia, and what funds are required to deal with these opportunities?

Answer. Last year the NHLBI implemented a Request for Applications program entitled, "Iron Overload: Cooley's Anemia and Other Disorders." This special grant program was intended to encourage research on novel approaches to treating iron overload. Four meritorious projects dealing with oral chelators were funded. Two more will be funded soon.

We have identified several areas of opportunity for making advances in the therapy of Cooley's anemia. The first is a multicenter clinical trial of new oral iron chelators as they are developed; the second is a program aimed at developing strategies for gene therapy; and the third is to explore using bone marrow transplantation as a treatment and to determine the selection of patients that would be appropriate candidates for this procedure.

These areas of opportunity would require funding of $4.1 million in FY 1991.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

MORTALITY DIFFERENCES AMONG BLACKS AND WHITES

Question. Dr. Lenfant, I understand that black men and women continue to show marked differences in mortality from heart diseases compared to white men and women. What action has the Institute taken to understand the reasons and to mitigate the disparities of mortality in minority populations?

Answer. The National Heart, Lung, and Blood Institute (NHLBI) is concerned about the differences in heart disease mortality in black men and women compared to white men and women. In an effort to understand the reasons for these differences, the NHLBI has supported and continues to support numerous studies to identify and understand factors contributing to the disparity in heart disease mortality observed in blacks and whites. Included among these studies are research on the comparatively high prevalence, incidence, and mortality of cardiovascular disease; research focusing on clinical concerns, such as survival after myocardial infarction; and, examination of the early natural history of atherosclerosis and essential hypertension. Other studies supported by the Institute investigate the roles of lifestyle and genetics as factors contributing to increased risk for heart disease. Results from these and other studies have contributed important data on black and white differences and similarities related to heart disease.

This information is disseminated to health professionals, patients, and the public for use in reducing the disparities of heart disease mortality in minority populations. Information from NHLBI supported research on what can be done to control cardiovascular risk factors is disseminated to all Americans through the Institute's national education programs. These efforts include the development of minority-focused radio and television spots which stress an important message, such as getting and keeping one's high blood pressure under control, minority-focused publications related to high blood pressure, cholesterol, smoking, and obesity; and, presentations to minority health professionals on the management of patients with high blood pressure and elevated cholesterol levels. The NHLBI Ad Hoc Committee on Minority Populations also serves as an important source of information to the minority community.

EDUCATION PROGRAMS

Question. Dr. Lenfant, would you describe for the Subcommittee recent activities of the Institute's Office of Prevention, Education, and Control?

Answer. The Office of Prevention, Education, and Control continues to operate comprehensive national programs in professional, patient, and public education. Recent activities in these programs range from development of definitive treatment guidelines for health professionals to production of mass media public service advertising campaigns. For example, in the cholesterol area, the initial focus on production of guidelines to treat high risk individuals was followed by development of a comprehensive report aimed at reducing cholesterol levels throughout the U.S. population. Recommendations have also been developed for improving the accuracy and reliability of blood cholesterol measurement and public screening. Work is underway to define treatment guidelines for high blood cholesterol in children and adolescents. A major effort in the high blood pressure area is the development and implementation of a special initiative, called "Strike Out Strokes (SOS)," to reduce stroke in the 11 southeastern states which form the "Stroke Belt," a region having a higher stroke mortality rate than the rest of the country. A special focus of this effort will be community programming and mass media strategies to reach the black population, since blacks in the Stroke Belt are twice as likely to die of stroke as whites in that region. Smoking education activities have continued the theme of "clinical opportunity," developing tools to help health professionals more effectively intervene with patients who smoke. Using this theme, a new guidebook was produced for respiratory care therapists, and a training videotape was developed for physicians.

In addition to its cardiovascular-related programs, OPEC operates the National Blood Resource Education Program, composed of major national blood-related voluntary and professional organizations. Recent efforts in this program include production of two major reports providing guidance for health professionals--one on use of red blood cells, platelets and fresh frozen plasma and the other on the use of autologous blood.

A new national education program was launched just one year ago. The National Asthma Education Program was begun in recognition of the growing prevalence of asthma in the U.S. and increasing mortality. The program is working on production of definitive guidelines for asthma diagnosis and treatment for physicians and other health professionals.

Question. What new initiatives do you plan to undertake in FY 91?

Answer. In FY 91, many of OPEC's current activities will be continued and intensified, and the possibility of new programs will be explored. For example, the asthma program has initiated a collaborative effort with the Department of Education to reach school administrative and health personnel. Broader collaboration in school health education is being considered for FY 91, especially in light of new recommendations on cholesterol-lowering in children and adolescents. In addition, NHLBI is analyzing the feasibility of starting a National Heart Attack Alert Program, focusing on the rapid identification and treatment of heart attack victims, with the goal of reducing morbidity and mortality.

Question. How much funding is included in the budget for education and prevention in FY 91?

Answer. The 1991 estimated level of funding for NHLBI's education and prevention programs is $6,056,000.

Question. How does this compare to FY 89 and FY 90?

Answer. The 1989 actual level of obligations for NHLBI's education and prevention programs was $7,341,000 and the estimated level for 1990 is $5,73[illegible],000 before reprogramming.

NATIONAL INSTITUTE OF DENTAL RESEARCH

STATEMENT OF HARALD LÖE, DIRECTOR

BUDGET REQUEST

Senator HARKIN. Next, Dr. Harald Löe, Director of the National Institute of Dental Research. And you want $140.52 million, that is 3.52 percent is what I have.

Dr. LÖE. Thank you very much, Mr. Chairman. Last year, I reported on the dramatic improvement in dental and oral health of America's children and young adults. And I also said that the reduction in the disease in these cohorts amounted to a saving in the Nation's dental bill of approximately $3 billion to $4 billion per year.

That was my good news.

The bad news was that older Americans were not doing well at all: That approximately 50 percent of the older segment of the population had lost all their teeth, and that those who still had teeth experienced the most tooth decay and the most severe periodontal diseases.

One of our initiatives during the 1990's will be to capitalize on the successes that we have had in the young and decisively address the problems of the aged. Our goal is to eliminate toothlessness in this country, and to put an end to the pain and the misery from oral disease among our senior citizens.

Our other major initiative relates to the so-called special care patients. These are people of all ages who have been victims of genetically determined diseases or congenital disorders. Examples are cleft lip and cleft palate; ectodermal dysplasias, where children are born with misshapen or missing teeth; osteogenesis imperfecta, which is another word for brittle bone disease. Other patient categories are those with autoimmune diseases. We have 4 million Americans suffering from Sjögren's syndrome, and other thousands suffering from canker sores, as we discussed last year.

A third group are those suffering from systemic diseases that, in various ways, reflect on the well-being of the mouth. The most prominent group here would be diabetic patients. Both juvenile and adult-onset diabetes have serious impacts on oral health, increasing susceptibility to periodontal diseases and other diseases affecting the mouth and the teeth. Various blood diseases are also included in this category.

The last group that I will mention are all the patients treated for cancer by radiation or by chemotherapy. Both these treatments can have devastating effects on the oral cavity.

Mr. Chairman, most people think of the NIDR as a two-disease institute: cavities and periodontal disease. This is a great misconception. It is true that our institute is special in that we deal with problems of all 250 million Americans.

PREPARED STATEMENT

We have shown you what we can do with tooth decay and periodontal disease; with your support, we look forward to showing you what we can do for the millions of special care patients and high-risk groups that are addressed in our initiatives.

Our request for 1990 is, as you said, $140,520,000, and I will be happy to answer any questions that you may have.

Thank you.

[The statement follows:]

STATEMENT OF DR. HARALD LÖE

Mr. Chairman, the National Institute of Dental Research is beginning the decade of the 1990's with a new Long-Range Research Plan that will take us to the year 2000. The new plan, available later this Spring, establishes two major initiatives that have become high priorities for the Institute.

The first initiative reflects our concern for "special care" patients. These are people whose oral health is affected by systemic diseases or systemic treatments. We are talking about Americans with such well-known conditions as diabetes, cystic fibrosis, lupus, and AIDS, as well as patients with rare or so-called "orphan" diseases such as scleroderma, a disease in which skin and connective tissue harden and shrink, leading to limited mouth opening; osteogenesis and dentinogenesis imperfecta, in which bones and teeth are poorly developed and subject to fracture; the ectodermal dysplasias, in which essential components of skin and teeth fail to develop properly; and Sjögren's syndrome, a condition of dry eyes and dry mouth, often complicated by arthritis, that primarily affects women. Sjögren's syndrome may not be so rare, since recent estimates suggest that up to 2 million Americans may be affected.

We would also include among special care patients individuals who have suffered oral complications because of cancer chemotherapy or radiation to the head or neck. In addition we intend to expand research on a number of primary oral conditions that merit increased attention such as oral cancers, certain chronic facial pain conditions, and disorders of taste and smell.

All told, special care patients add up to millions of Americans. We have been alerted to their needs because the patients and their families themselves have formed organizations to address those needs and because their health problems are increasingly coming under research attack by NIDR-supported scientists. Indeed, we foresee a time when dentists in America may be the primary point of entry into the health care system for many people, providing diagnosis as well as treatments or referrals for many of these conditions.

I can illustrate that broadening of the scope of the dentist with an account of what happened recently during a visit by a Congressman to a dental clinic affiliated with one of the country's leading dental schools. The delegation had stopped to observe a dental examination in progress in which the dentist had noted a spot on the tongue of the patient. Later, the Dean of the dental school, who had also observed the patient, confided that while positive test results would be needed to confirm the diagnosis, the patient almost certainly had Kaposi's sarcoma and that this sign may well have been the first indication that the patient, a young man, was infected with the AIDS virus.

The AIDS epidemic is a good example of the extent to which oral health research has expanded to include the full range of diseases and disorders that affect the oral tissues. In our new Long-Range Research Plan we use the phrase "from AIDS to Xerostomia" (the technical term for dry mouth) to express this broadened capability. Recent indicators of our progress include:

- The development of an animal model for osteogenesis imperfecta and isolation of the genes for major bone growth factors involved in bone and joint diseases. These studies may lead to the use of specific growth factors to reverse the connective tissue damage that is seen, for example, in osteoarthritis.

- Use of the drug pilocarpine to treat Sjögren's syndrome and other conditions of dry mouth in which some functioning salivary gland tissue remains. Researchers are studying the basic defect in Sjögren's syndrome, noting changes in saliva and the presence of circulating antibodies that are directed against the body's own tissues as markers of disease activity.

- Development of sensitive tests indicating that human papilloma virus (HPV) is present in a very high percentage of cancers affecting the lining and floor of the mouth, and the tongue, larynx, and pharynx of patients. This association will be followed up with analyses of how the virus may interact with other factors, such as tobacco use, in causing oral cancer.

- Clinical studies of the use of permanent dental implants instead of removable dentures in young patients with congenital absence of teeth (as seen in cases of ectodermal dysplasia) as well as in older patients who have lost all their teeth.

- Development of experimental models of chronic pain due to nerve injury (neuropathy). An unexpected finding was considerable spontaneous nerve activity in the damaged nerves. This could account for the heightened sensitivity and severity of pain experienced by patients with diabetic neuropathy and other forms of neuropathy.

In terms of progress in AIDS research, I would add:

- Continued evidence that oral signs and symptoms may be the first indications of infection with HIV. The fungal disease, candidiasis, appears to be the most prevalent oral condition associated with HIV infection, followed by "hairy leukoplakia," a lesion seen most frequently on the tongue. Because hairy leukoplakia is considered predictive of frank AIDS, investigators are increasing efforts to determine its cause and develop means of early diagnosis, treatment, and prevention.

- Issuance of a Request for Applications to explore the role of saliva in HIV infection. We hope to award several grants to expand on earlier studies indicating that saliva probably plays little or no role in the transmission of HIV, and may, in fact, contain a factor that inhibits the infectivity of the virus.

- Refinements in transgenic mouse models of HIV. In collaboration with the National Institute of Allergy and Infectious Diseases, NIDR scientists have inserted individual HIV genes in mice so that models are available for the study of juvenile AIDS, fetal abortion, and HIV-associated kidney disease.

o Expanded collaboration with the Walter Reed Army Institute of Research in a natural history of oral manifestations of HIV infection in military personnel. The new research activities include developing treatments for oral conditions and studies of the severe periodontal disease seen in some patients.

Our second major initiative for the nineties is one we have discussed in previous hearings before this Committee. The Research and Action Program for Improving the Oral Health of Adults and Older Americans was developed in response to findings from recent NIDR nationwide surveys of oral health. Our adult survey established that Americans 65 and older have the most severe oral health problems of any age group, with rates of toothlessness better than 40 percent and with extensive caries and periodontal diseases among those who still have teeth. We have defined the goals of the Research and Action Program to be the elimination of toothlessness among future generations of Americans and the prevention of further deterioration of the oral health of individuals with already compromised dentition--with a target date for accomplishment set for the next 20 years. NIDR will pursue basic and clinical research on normal age-related changes in the oral tissues as well as changes due to oral and systemic disease and treatments. "Action research" will involve NIDR in the transfer of laboratory findings to public and professional use through clinical trials, demonstration research, and similar efforts. Much of the research effort will focus on the prevention and treatment of dental caries and the periodontal diseases since these are the major causes of tooth loss. Thus by giving the program high priority we are expressing the need to finish the job of eliminating the two diseases that have for so long dominated dentistry.

In the past year we have worked closely with the Centers for Disease Control, which will assume responsibility for working with state and local health agencies in implementing oral health promotion and disease prevention activities. In addition, we have gained the enthusiastic support of other government agencies, including the Indian Health Service and the Health Resources and Services Administration. The Assistant Secretary for Health has now requested that the Program be identified as a Public Health Service-wide activity involving a chartered interagency task force. We believe that such a focus will greatly facilitate a coordination and collaboration that will eventually involve the dental professional community, the private sector, community leaders, and consumer groups.

The Research and Action Program is emphasizing the importance of identifying individuals of any age who are at risk for oral health problems for whatever reason--dental, medical, or socioeconomic. Thus the program complements the Special Care Patient initiative but adds demographic factors such as age, education and income in determining risk. We are especially mindful of the need to improve the oral health of racial and ethnic minorities. Past surveys have been limited in sampling and analytic techniques, often reporting data for Whites and "non-Whites" or "Blacks and others." Even within the limited compass of these surveys, however, it is clear that racial and ethnic minorities generally fail to match the level of oral and general health attained by the average American. Further, if interventions designed to prevent disease and promote health are to be effective, they must take into consideration cultural values, language, financial means, access to services, and other variables affecting health care. Last May we invited a distinguished group of Black, Hispanic, and Native American health professionals to discuss health issues and ways to resolve them. We have incorporated their ideas in our new research plan and have increased efforts to enhance recruitment of racial and ethnic minorities into oral health research.

We have held similar meetings with representatives of private industry and oral health researchers from other countries. The intent of these meetings was to define areas which could benefit from collaboration, not only to facilitate the conduct of research and research training, but to broaden the base for support in ways that could benefit all parties. One outcome of these meetings has been the decision to form a liaison group made up of grantees, private sector representatives, and NIDR staff which would meet periodically to discuss ongoing research with the potential for collaboration. NIDR is committed to such approaches as ways to assure that America maintains its leadership and competitive edge in biomedical research worldwide.

We have also incorporated into our research plan a variety of support mechanisms that have already proven their worth in dental research. These include the continued use of research centers and other large grant mechanisms as recommended by an external advisory group reporting to this Committee in 1985. At present we are supporting 19 research centers. This will be increased to 21 later this year with the award of the two new clinical core research centers that were made possible through the support of Congress. Core centers will be especially valuable to academic institutions eager to enhance their research potential.

The need to ensure an adequate pool of research investigators also dictates our continued emphasis on research training and career development awards. In particular, the 5-year Dentist-Scientist Award has been extremely successful and we are graduating our first class this June. We have reached our "steady state" goal of having approximately 125 candidates enrolled in the system at any one time and, from the qualities of the candidates we are seeing, feel confident that these young men and women will make major contributions to dental research and education throughout their careers. Through them, their mentors, and other leading oral health research investigators active today, we are seeing a profession evolve from a primary concern with two still highly prevalent, painful, and costly dental disorders to one prepared to address all the diseases and disorders that affect all the orofacial tissues.

Mr. Chairman, the FY 1991 request for the National Institute of Dental Research is $140,520,000. I will be happy to answer any questions.

BIOGRAPHY OF DR. HARALD LÖE

July 19, 1926, Steinkjer, Norway

Education: Oslo University, Norway, D.D.S., 1952: Dr. Odont, 1961

Professional History: 1974-1982, Dean and Professor of Periodontology, School of Dental Medicine, University of Connecticut, Farmington. 1972-1974, Professor of Dentistry and Director of the Dental Research Institute, University of Michigan, Ann Arbor. 1962-1972, Professor of Dentistry and Chairman, Department of Periodontology, Royal Dental College, Aarhus. 1971-1972, Associate Dean and Dean-elect, Royal Dental College, Aarhus. 1966-1967, Visiting Professor of Periodontics, Hebrew University, Jerusalem. 1956-1962, Research Associate, Norwegian Institute for Dental Research, Oslo. 1960-1962, Associate Professor, Department of Periodontology, School of Dentistry, Oslo University, Oslo. 1959-1962, University Research Fellow, Oslo University, Oslo. 1957-1958, Fulbright Research Fellow and Research Associate, Department of Oral Pathology, University of Illinois, Chicago. 1952-1955, Instructor in Operative Dentistry, School of Dentistry, Oslo University, Oslo.

Honorary Doctorate Degrees: University of Toronto, 1989; Royal Dental College, Copenhagen, 1988; University of Medicine & Dentistry of New Jersey, 1987; University of Maryland, 1986; University of Bergen, Norway, 1985; Georgetown University School of Dentistry, Washington, D.C., 1983; University of Lund, Sweden, 1983; Catholic University of Leuven, Belgium, 1980; University of Athens, Greece, 1980; Royal Dental College, Aarhus, Denmark, 1980; University of Gothenburg, Sweden, 1973.

Honors, Awards: Honored by His Majesty the King of Norway (Royal Norwegian Order of Merit), 1989; U.S. Surgeon General's Exemplary Award Medal, 1988; Swedish Dental Society International Prize, 1988; Honorary Professorship, Medical Sciences University of Beijing, 1987; The Royal Dental College, Copenhagen, Denmark, 1987; Goldstein Lecture, Emory University, 1986; Member, National Academy of Sciences, Institute of Medicine, 1985; Benjamin J. Robinson Lecture, University of Maryland, 1985; Alfred C. Fones Medal for Outstanding Achievement in the Service of Humanity, 1984; International Award of the Friends of the University of Connecticut School of Dental Medicine, 1983; Lister Hill Memorial Lecture, University of Alabama, 1983; Daniel F. Lynch Award, Dental Society of Greater Waterbury, 1983; International Lecturer of the Year Award, Academy of International Dental Studies, 1983; Gold Medal, University of Ghent, 1982; Centennial Award, University of California School of Dentistry, 1982; Award of Merit, Hartford Dental Society, 1982; Irving Glickman Memorial Lecture, Tufts University, 1979; William J. Gies Award, American Academy of Periodontology, 1978; Arthur Merritt Memorial Lecture, Baylor University, 1977; Certificate of Achievement, Connecticut Society of Periodontists, 1976; Massachusetts Dental Society International Award, 1973; honored by Her Majesty the Queen of Denmark (Knight of Danebrog), 1972; International Association for Dental Research Award for Basic Research in Periodontics, 1969; Honorary memberships in several professional societies around the world.

Other Professional Activities: Author of more than 260 scientific articles; international lecturer; honorary member and elected fellow of scientific and learned societies here and abroad.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

THE FLUORIDE DEBATE

Question. I understand that a clinical trial on the health effects of fluoride has raised some troublesome new issues on the safety of using fluoride in drinking water. The study uses three groups of rats: one group is administered fluoride in their water 1 part per million; one group is administered fluoride 25 parts per million; and the third group is administered fluoride 175 parts per million. In this group of rats, four have developed bone cancers; in the second group, one rat developed bone cancer.

What can you tell us about the health effects of fluoride in the drinking water? Are these research results cause for alarm?

Answer. There are no known adverse health effects from consuming optimally fluoridated water. Unsubstantiated claims that water fluoridation is responsible for cancer, birth defects, osteoarthritis, kidney disease, premature aging, allergies, Alzheimer's disease, and AIDS have been refuted repeatedly in peer-reviewed journals.

Dental fluorosis is a clinically detectable change in enamel structure resulting from systemic exposure to fluoride of the enamel-forming organ during tooth formation. The condition develops during the formation of the teeth and does not worsen with age. The enamel changes range from barely perceptible white spots in cases of mild fluorosis to unsightly discoloration and pitting of teeth in severe fluorosis. While optimally fluoridated water can produce mild fluorosis in a small percentage of children, the level of fluoride necessary to produce objectionable fluorosis is several times higher than that recommended for prevention of tooth decay. Historically, severe fluorosis has occurred almost exclusively in areas of the country with excessively high levels of naturally occurring fluoride in the groundwater.

The NIDR measured dental fluorosis during the 1986-87 survey of dental health in American schoolchildren, providing the first national data on fluorosis in children. The survey measured fluorosis resulting from all forms of fluoride exposure, not just water fluoridation. The findings showed that 22 percent of youngsters had fluorosis, almost all of it in the very mild and mild categories. In its mildest forms, fluorosis is difficult for even dentists to detect. Only 1 percent of children nationwide had moderate fluorosis, and even fewer (0.3%) had severe fluorosis. Fluorosis was detected in children who had never lived in a community with fluoridated water as well as in children who did.

Since the NIDR survey provided the first national evaluation of fluorosis in children, no direct comparison can be made to determine if the prevalence of fluorosis is changing. But data have been collected on fluorosis in a number of communities since 1940. Using these for comparison, it appears there probably has been a slight increase in the very mild and mild forms of fluorosis in this country, but no increase in more advanced forms of the condition. The overall severity of fluorosis documented among American schoolchildren in 1987 was well below the level considered of public health significance. It is important, however, to continue to monitor fluorosis in U.S. children, given the availability of fluoride in many forms.

The National Toxicology Program (NTP) has released preliminary data from a study on the possibility of a relationship between sodium fluoride and cancer in rodents. The 2-year study exposed rats and mice to very high doses of sodium fluoride. This standard method enables scientists to detect rare events. At the highest levels, which greatly exceed the amount used to fluoridate drinking water, there were some cases of osteosarcoma found in Fisher rats. At this time, the data have yet to be analyzed, interpreted by experts, or subjected to peer-review by outside scientists. We are also aware of preliminary results from another 2-year rat bioassay by the Proctor and Gamble Company in which Sprague-Dawley rats received high doses of sodium fluoride in their diet. This study found no evidence of any benign or malignant bone tumors. Like the NTP study, however, the Proctor and Gamble study must still undergo scientific peer-review and publication. In short, the entire data must be fully analyzed to determine their significance. Until the completion of this process, the many benefits of fluoride warrant continuation of the present policy designed to prevent tooth decay. It should be pointed out that, after 45 years of water fluoridation involving scores of human epidemiological studies both in the United States and in other countries, there has not been any evidence that shows a relationship between fluoridation and cancer or other diseases in humans.

CLINICAL DENTAL RESEARCH CORE CENTERS

Question. Last year's Senate report provided funding to add up to three Clinical Dental Research Core Centers. These centers would have the principal objective of promoting research that would expedite the translation of basic scientific knowledge into better treatment techniques. Will you be able to establish these centers in FY 1990?

Answer. Early in FY 1990, the NIDR issued a Request for Applications (RFA) for Clinical Dental Research Core Centers to facilitate clinical research relevant to the pathogenesis, diagnosis, early detection, control, and treatment of oral diseases, disorders, and/or dysfunctions. Responses to the RFA are expected in March 1990. Depending on the outcome of the peer review process, the NIDR anticipates the award of two core centers later this fiscal year.

LONG RANGE RESEARCH PLAN

Question. I understand that your Institute is developing a Long Range Research Plan for the 1990's that will move beyond the traditional focus on cavities and periodontal disease. Please describe for the Committee the basic content or thrust of the new Long Range Research Plan for the 1990's.

Answer. The Plan for the Nineties emphasizes the broadened scope of oral health research. When the NIDR was established in 1948, the problems of tooth decay and periodontal diseases were paramount. NIDR pursued research targeted to these conditions, but also began to support research in developmental biology, mineralized tissue research, soft tissue diseases, pain, and other areas, which are reviewed in the new Plan. With the developments in genetics and molecular biology, as well as the AIDS epidemic, there has been a further expansion in the breadth and depth of oral health research. These developments, plus recent epidemiologic surveys, have been the impetus for two broad initiatives described in the last chapter of the Plan: The first initiative concerns the need to address the oral health problems of "special care patients." These are individuals who are at risk for oral health problems because of an underlying medical or handicapping condition such as diabetes, AIDS, or certain genetic disorders, or because of medical treatments, such as radiation and chemotherapy for cancer. Our investigators are studying the basic mechanisms underlying many of these conditions and developing approaches to prevent or treat the oral complications.

The second initiative relates to the need to come to the aid of individuals or groups at high risk for oral diseases and tooth loss for health or socioeconomic reasons. Our concerns here are for older Americans, for members of racial or ethnic minorities, and other individuals or groups susceptible to oral health problems because of health reasons, or because of limited education or access to care. We need to determine who is at risk and why, and intervene with the best preventive and treatment approaches available.

DENTAL SCHOOL ADMISSIONS

Question. During the 1980's we saw a significant reduction in dental school admissions, which many suggested was the reaction to a glut of dentists in the market. What can you tell us about the supply of dentists in the United States today?

Answer. The number of dentists in the United States increased rapidly during the decade of the 1980's, from approximately 126,000 in 1980 to 147,000 in 1988. In the 1990's, however, very little increase is expected. The number of dentists should peak toward the end of the 1990's to about 155,000 and then decrease to about 141,000 by 2020.

Question. Has there been a turn around in dental school admissions from the previous declines of the 1980's?

Answer. Since 1978, the number of first-year students in dental schools has decreased by 37 percent, from 6,301 to 3,979. Throughout this time period, the annual rate of decrease in class size has been relatively constant at 4 or 5 percent. The last year for which data are available is typical: For the entering class of 1989, the number of first-year places decreased by 217, or 5.2 percent.

MATERIALS RESEARCH CENTERS

Question. What is the status of the Dental Materials Research Centers, which you discussed last year?

Answer. Eighteen applications were received in response to our solicitation, and we were able to make three awards. These are at the Universities of Florida and Michigan and at the American Dental Association Health Foundation at the National Institute of Standards and Technology.

The Specialized Materials Science Research Centers program has attracted outstanding materials science and engineering investigators, including those with no prior experience in dental research, to address problems in dental materials in the broadest sense. These materials scientists are collaborating with toxicologists, engineers, chemists, biologists, and clinical researchers to design and develop biocompatible restorative materials, adhesives, protective coatings, and novel products for use in maxillofacial prostheses for oral cancer and trauma victims.

PREDICTORS OF AIDS

Question. Last year you indicated that oral lesions may occur early in the course of an AIDS infection and that these lesions could be used to predict the onset of the more serious aspects of this disease. Has your research confirmed these ideas?

Answer. So far, the concept of using oral lesions to predict the onset of frank AIDS seems valid. In fact, two distinct, clinically recognizable lesions may serve as reliable indicators of oncoming AIDS. One of these is the lesion called hairy leukoplakia, which was discovered by NIDR grantees; the other is a fungal infection by the organism Candida albicans, which is commonly present in most individuals but does not usually cause disease unless patients are immunocompromised. NIDR-supported investigators found that, when hairy leukoplakia is seen in apparently healthy but HIV-seropositive individuals, the development of frank AIDS occurs within the next 16 months in nearly half the patients, and within 30 months in about 80 percent of patients. Although the development of frank AIDS has not been carefully documented in healthy but HIV-seropositive individuals who have oral candidiasis infections, the pattern generally follows that of the patients with hairy leukoplakia.

SALIVA AND HIV

Question. Last year we heard that there were substances in saliva that would prevent HIV infection. What is the status of that research?

Answer. Preliminary findings continue to support the concept that a component of saliva from the submandibular/sublingual salivary glands reduces the infectivity of HIV. In related laboratory experiments, salivary factors have been shown by NIDR-supported investigators to reduce the level of herpes simplex virus Type I. These investigators plan to extend the research to include other types of herpesvirus and HIV. An RFA to further characterize the salivary substance and determine its mechanism of action on HIV was issued last year; 13 applications were received, and we expect to make several awards this year.

MERCURY AMALGAMS

Question. Is there any truth to the reports that mercury from dental amalgams used to fill teeth is hazardous to patients?

Answer. We have critically reviewed the literature on the potential hazards in using mercury in dentistry. We conclude that, while there is consistent evidence indicating release of mercury vapor from restorations during chewing, tooth brushing, and other activities, proof of a causal link of this source of mercury to any human health problem is lacking.

The most common sources of mercury are foods, contaminated air, occupational exposure, and certain drugs and ointments. It is very difficult to differentiate the effect of one of these sources from that arising from dental amalgam. Examination of blood and urine levels of mercury of individuals with and without amalgam fillings has shown the contribution from amalgam fillings to be negligible. A recent NIDR-supported study confirms earlier findings. Neither mercury itself nor a metabolite, methyl mercury, could be detected in the blood or urine of any of 31 patients over a 1-year period after placement of up to eight mercury-containing amalgam restorations.

There is no documented evidence for recommending that the use of mercury-containing dental amalgams in restorative dentistry be discontinued. The removal of dental amalgam can only be recommended in those patients who have true hypersensitivity to mercury or other constituents. The Institute continues to solicit applications for research on this topic.

IMPLANTS

Question. What is new on dental implants?

Answer. Dental implant therapy has become a fairly well-accepted approach as a substitute for dentures in healthy individuals. The NIDR is now beginning to study the efficacy of these devices in patients with medical conditions. For example, we are currently conducting an intramural clinical trial on the efficacy of implant therapy in ectodermal dysplasia patients, who have congenitally missing teeth. The Institute also intends to support research on the efficacy of dental implants in a population of elderly American veterans who have diabetes. These patients tend to lose teeth early as a result of periodontal disease.

Although dental implants placed in the front of the lower jaw bone have an extremely high rate of success, the success of implants in other parts of the lower or upper jaws is somewhat less predictable, because of variation in the type of supporting bone. We plan to conduct animal studies on implants placed in the different regions of the jaw bone.

An impressive amount of data has accumulated to show that implants provide suitable prostheses for full dentures. Currently, practitioners are providing implant replacements for groups of missing teeth, where the implants must function in conjunction with natural teeth. We anticipate that artificial dental implants will eventually supplant traditional crown and bridge therapy, and we plan to study the efficacy of free-standing implants for single tooth replacements.

SELF-CARE AMONG THE ELDERLY

Question. Are any behavioral researchers studying whether older people can be educated, or motivated, to take better care of themselves in order to prevent oral diseases?

Answer. Yes; increasing disease-preventive behaviors is an important aspect of the Research and Action Program that NIDR is undertaking for improving the oral health of adults and seniors. Initial results from several new research projects are promising. For example, one study conducted with older adults attending senior centers in the Pacific Northwest found that seniors taught or persuaded to improve their personal oral hygiene practices actually maintained these improvements much more consistently than did younger adults. These findings contradict widely held assumptions about the futility of trying to get older people to change personal health practices.

NUTRITION RESEARCH INITIATIVE

Question. Would you please tell us about NIDR's new initiative to enhance nutrition research?

Answer. Expansion of the NIDR's nutrition research activities has been recommended by several expert panels and advisory committees.

The nutritional status of an individual appears to influence the susceptibility and progression of oral diseases such as caries, periodontal disease, and herpesvirus infection. Salivary gland disorders, oral cancer, and birth defects such as cleft lip and palate are also affected by nutritional factors. Nutrients can affect growth and metabolism of oral pathogens as well as host cell repair and immune responses.

A Program Announcement on "Nutrition and Oral Health" was issued in 1989 to encourage submission of research applications on the role of diet and nutrition in the development and maintenance of oral and craniofacial tissues and in the prevention of oral diseases. It encouraged interdisciplinary collaboration and highlighted the importance of studies involving women, the elderly, and other high-risk populations.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

LONG-RANGE RESEARCH PLAN

Question. Dr. Loe, I noted in your testimony that the Institute's newly established Long-Range Research Plan includes a "major initiative" for the 1990's to improve the oral health of adults and older Americans. This is a commendable initiative. I understand that your surveys have shown that persons age 65 and older have the most severe oral health problems of any age group. Given this, does the budget for FY 1991 include sufficient funding to implement this "major initiative"? How much is included in the FY 1991 budget to support research into the oral health of older Americans? How does this compare to funds spent in FY 1989 and 1990?

Answer. Strictly defined, research related to the oral health of older Americans is estimated to be $5.9 million for FY 1991, compared to $5.5 million in FY 1989 and $5.7 million estimated for FY 1990. The Research and Action Program comprises more than aging-related research, however. Our intent is to address the oral health problems of adults as a whole, with particular attention to those at risk for tooth loss for reasons of health or socioeconomic factors. If we include clinical research on such adult oral health problems as periodontal diseases, root caries, primary and recurrent coronal caries, and add in epidemiologic studies and models of tooth loss, the amount expended for the Research and Action Program was close to $15 million in FY 1989. Similar expenditures are anticipated for FY 1990 and 1991. In order to maintain this level of support, the NIDR will encourage research applications through the use of program announcements, requests for applications, and requests for proposals.

FLUORIDE STUDY

Question. Dr. Loe, what conclusions can be drawn from the recently reported National Institute on Environmental Health Sciences study concerning fluoride? How should I respond to my constituents in Pennsylvania who express concern about this report?

Answer. The National Toxicology Program (NTP) has released preliminary data from a study on the possibility of a relationship between sodium fluoride and cancer in rodents. The 2-year study exposed rats and mice to very high doses of sodium fluoride. This standard method enables scientists to detect rare events. At the highest levels, which greatly exceed the amount used to fluoridate drinking water, there were some cases of osteosarcoma found in Fisher rats. At this time, the data have yet to be analyzed, interpreted by experts, or subjected to peer-review by outside scientists. We are also aware of preliminary results from another 2-year rat bioassay by the Proctor and Gamble Company in which Sprague-Dawley rats received high doses of sodium fluoride in their diet. This study found no evidence of any benign or malignant bone tumors. Like the NTP study, however, the Proctor and Gamble study must still undergo scientific peer-review and publication. In short, the entire data must be fully analyzed to determine their significance. Until the completion of this process, the many benefits of fluoride warrant continuation of the present policy designed to prevent tooth decay. It should be pointed out that, after 45 years of water fluoridation involving scores of human epidemiological studies both in the United States and in other countries, there has not been any evidence that shows a relationship between fluoridation and cancer or other diseases in humans.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

STATEMENT OF DR. ANTHONY S. FAUCI, DIRECTOR

SUMMARY STATEMENT

Senator **HARKIN**. Dr. Fauci, we welcome you. I see that your request is $886.88 million, for a 6.47-percent increase. Dr. Fauci, welcome. Please proceed with your statement.

Dr. **FAUCI**. Thank you, Mr. Chairman, Senator Bumpers.

We are living in an era of great research opportunities as well as unprecedented scientific opportunities. These opportunities are possible mainly because of advances which result from basic research.

We are currently reaping the benefits of investments in basic biomedical research of the past decade, and likewise the basic research we perform today is a critical investment in the accomplishments of tomorrow.

In particular, the rapidly evolving fields of immunology and microbiology are providing new opportunities for creative and high-yielding research. NIAID scientists, for example, were quick to exploit the possibilities presented by a basic research technique called the polymerase chain reaction which selectively amplifies genetic material. This technique can detect very early HIV infection and NIAID intramural scientists have recently adopted it for use as a diagnostic test for the elusive agent of Lyme disease.

Another important accomplishment of the 1980's built on the basic research of NIAID scientists which we will see come to fruition in the 1990's is the ability to screen blood for hepatitis C virus, formerly called non-A, non-B hepatitis, the principal cause of transfusion-associated hepatitis.

In addition, molecular biological techniques have made possible new candidates for a pertussis vaccine with potentially minimal toxicities. Furthermore, recent advances in tissue typing at the molecular level, together with the development of more specific and effective immuno-suppressive regimens, may well revolutionize the field of organ transplantation in the next decade or two.

Nowhere do we have better examples of the payoffs from basic and clinical research investments than with AIDS. Results from recent studies indicate the benefits of HIV-infected individuals prior to the onset of symptoms, as well as the real possibility of an effective vaccine in the decade of the 1990's.

In a more immediate and practical application of our drug development program, we have launched our community programs for clinical research on AIDS this past year, and it promises to be quite successful in providing a clinical trial apparatus at the grassroots community level.

NIAID is in a unique position to use the emerging opportunities in biomedical research to provide the means to prevent, and even to completely eliminate certain diseases from the United States and the world. As you know, Mr. Chairman, the toll of human life and suffering is enormous, and new and reemerging diseases continue to challenge us.

PREPARED STATEMENT

Thus, we at NIAID look to the 1990's with resolve, energy, and enthusiasm. I am confident that we can meet the challenges of the 1990's through the knowledge that we have gained, and will continue to gain, by investing in basic and ~~clinical~~ research in allergy, immunology, and infectious diseases.

Mr. Chairman, the fiscal year 1991 budget request for NIAID is $886,875,000. I would be pleased to answer any questions you may have.

[The statement follows:]

STATEMENT OF DR. ANTHONY S. FAUCI

We live in an era of great scientific accomplishments, but it is also an era of unprecedented emerging research opportunities. These opportunities have been made possible in large part by advances in biotechnology and molecular biology, many of which are the fruits of NIAID-supported basic research. Without question, we are now reaping the benefits of our investment in basic research of past decades. Likewise, the basic research of today is a vital investment in the accomplishments of tomorrow.

In particular, during the decade of the 1980s, the rapidly evolving fields of immunology and microbiology have provided new opportunities for creative and high-yielding research. For example, last year I mentioned a new research technique called the polymerase chain reaction, or PCR, that uses the polymerase enzyme from a microorganism living in the warm waters of geysers and hot springs. I explained how PCR can multiply minute quantities of genetic material in a tissue sample, making it possible to detect disease-causing microorganisms that otherwise are hidden in the human body. Researchers who were working on the microbiology and molecular biology of that unusual bacteria called Thermus aquaticus had no idea of the ultimate implications of their research.

Over the past year, AIDS research has brought PCR to the forefront where it has been used to detect very early HIV infection. In fact, its value is much broader than AIDS diagnosis, and NIAID intramural scientists have been among the first to explore its possibilities. They have adapted PCR to a diagnostic test for the elusive agent of Lyme disease. Carried by ticks and recognized only 15 years ago, Lyme disease is now the most commonly reported arthropod-borne disease in the United States. If not treated, it can cause great pain and disability from chronic arthritic, neurologic, or cardiac symptoms. A major roadblock to effective treatment has been the lack of reliable tests to diagnose the disease during early infection. Development of a sensitive new test using PCR should greatly facilitate accurate diagnosis.

Another important accomplishment of the 1980s was built on basic research by NIAID intramural scientists. In the 1970s, they identified an agent that they called non-A non-B hepatitis virus and determined that it was the principal cause of transfusion-associated hepatitis. They characterized the agent by extensive basic research studies using chimpanzees, the only animal host other than man susceptible to the agent. Using this information, other scientists in 1989 succeeded in developing a test that, for the first time, detects individuals who are infected with the agent, now called hepatitis C virus. The test will make it possible to screen blood donors and prevent transmission of hepatitis C, which often leads to chronic hepatitis and, in some cases, to cirrhosis and liver failure.

Particularly noteworthy in its ability to create and capitalize on research opportunities that impact on many scientific disciplines, the NIH intramural research program allows established investigators to work in an undistracted environment that allows for intellectual risk-taking. Basic and clinical research are linked in a manner that makes possible a rapid response to emerging problems. In addition, it has provided training for many, if not most, of the outstanding biomedical research scientists in the United States. In fact, two winners of the 1989 Nobel Prize in Physiology and Medicine were trained at the NIH, one in the NIAID intramural program. This investment has enabled the United States to take the leadership role in biomedical research, particularly in immunology, microbiology, and AIDS research.

One exciting example of the dividends of basic research in immunology is the emergence of new insights into the immune mechanisms and cell types involved in the rejection of organ transplants. Scientists now have a sound basis for developing immunosuppressive agents that are more effective and less toxic than those presently in use. Recently, NIAID grantees produced a hybrid molecule linking diphtheria toxin to interleukin 2, one of several powerful chemical substances known as cytokines that are produced by the immune system. This molecule carrying its toxic ammunition acts as a "magic bullet," specifically binding to and eliminating the cells responsible for transplant rejection. This is only one of several new immunosuppressive measures being developed to improve the success rate for organ transplantation.

Other cytokines also hold promise as therapeutic agents. We reported last year that NIAID investigators showed that interleukin 4 was a potent inducer of the IgE molecule, which triggers allergic and hypersensitivity reactions. These scientists have now prevented the elevation of IgE levels in animals by administering a monoclonal antibody that binds to interleukin 4 and thus blocks its ability to stimulate IgE production.

Monoclonal antibodies, developed in the 1970s, provide another example of how the investment in basic research is paying off today. In the 1980s, monoclonal antibodies opened the door to remarkable new approaches to preventing, diagnosing and treating disease, and the benefits will continue to multiply in the 1990s and well into the next century.

Nowhere do we have better examples of the payoffs from basic research investments than in AIDS research. The advances in understanding AIDS have been extraordinary, and 1989 alone has produced results from several important studies that may mean longer and healthier lives for those infected with the AIDS virus and bring us closer to development of an effective vaccine.

Two NIAID studies have shown the value of early intervention in treating persons infected with the human immunodeficiency virus (HIV). These studies showed that AZT, the antiviral drug approved in 1987 for treatment of persons with AIDS, significantly slows progression of disease in people who are infected with the virus and whose levels of T4 cells have declined modestly, but who have no symptoms or have the earliest symptoms of HIV infection.

These results strengthen the argument that early recognition of infection can be extremely beneficial since a doctor can closely monitor the immune system of the infected person and advise early treatment with AZT, other antiviral drugs, or drugs to prevent opportunistic infections.

A third NIAID study revealed that AZT was as effective and less toxic at half the dose originally recommended. As a result, the FDA in January 1990 approved changing the labeling for the drug. By using a lower dose, fewer patients may have to discontinue AZT therapy because of serious side effects.

In the meantime, the number of drugs being studied in AIDS clinical trials continues to climb--approximately 35 drugs or combinations of drugs are presently being tested by NIAID-supported investigators in more than 100 studies being done in 47 AIDS Clinical Trials Units throughout the United States. Fifteen of these Units conduct clinical trials exclusively in children, and seven of the adult Units also do pediatric studies.

The results reported last year show the importance of carefully controlled clinical trials. To HIV-infected persons, trials also mean earlier access to promising drugs. To expand that opportunity to those underrepresented in trials in the past, NIAID has funded 18 Community Programs for Clinical Research on AIDS. These programs, conducted at the grass roots level, complement the AIDS Clinical Trials Units at large academic medical centers. They reach out to HIV-infected blacks, Hispanics, i.v. drug users, and women in 14 American cities where the impact of AIDS is severe.

Patients seeking access to clinical trials usually ask--Where can I go to enter a trial? What drugs are being tested for someone with my symptoms and stage of disease? In order to provide that information quickly and easily to any interested person, NIAID cooperated with other Public Health Service agencies to establish the AIDS Clinical Trials Information Service in May 1989. By dialing 1-800-TRIALS-A, the caller reaches a trained specialist who gives information about NIH-sponsored as well as other trials.

AIDS vaccine research took a significant step forward this year. Findings from several animal studies have dispelled early doubts about the scientific feasibility of an AIDS vaccine. In these studies, a prototype AIDS vaccine made from a virus that infects rhesus monkeys has protected the animals from getting AIDS. Also, the monkeys protected by the vaccine give researchers a long-awaited opportunity to study an AIDS-resistant immune system in order to characterize the biological features responsible for warding off the infection.

As you can see, we are beginning to reap dividends from the intensive investment in AIDS research, an investment that will have a positive impact not only in AIDS, but also in other areas of research. For example, research on antivirals and other antimicrobial agents, given great impetus by the AIDS epidemic, will in the 1990s lead to treatments for other sexually transmitted viral diseases and for the opportunistic infections that take the lives of so many immunosuppressed cancer patients and organ transplant recipients.

In the last few years, basic research has provided us with an increasingly sophisticated understanding of infectious agents, of the immune system's remarkable capacity to produce powerful, appropriate and self-limiting responses to infection, and of the diseases that can affect the immune system itself. This understanding has been responsible for the remarkable progress in AIDS research. It has also presented biomedical science with an extraordinary array of emerging opportunities. As a scientist and administrator, I must constantly set priorities after carefully considering the opportunities for progress and the urgency of the problem.

One urgent problem we face in this country is the disproportionate number of primarily black and Hispanic children in the inner cities who are suffering and dying from asthma. There is mounting evidence that asthma mortality and morbidity rates are increasing in the United States, despite advances in therapeutics and development of patient-education strategies. These rates are particularly high in the inner cities. NIAID will fund a network of centers as part of a national cooperative inner-city asthma study. These centers will determine the most effective ways to reduce asthma morbidity in these children.

Another urgent problem that I have discussed in past years is the terrible toll taken by sexually transmitted diseases particularly on young women, in whom we are seeing increases in infertility, and on babies, who are often left mentally retarded or otherwise impaired by infection before and during birth. Today, achievements in basic research provide emerging opportunities to develop vaccines and improve diagnostic tests and treatments for many of these diseases. To take advantage of this, NIAID will fund STD Cooperative Research Centers.

NIAID is in a unique position among NIH Institutes to use the emerging opportunities in biomedical research to provide the means to prevent and even to completely eliminate certain diseases from the United States and the world. Availability and strategic use of a vaccine eliminated one of the most severe infectious diseases, smallpox, from the entire world. The combined use of vaccines and antibiotics has dramatically reduced the impact of other infectious diseases, such as polio, diphtheria, pertussis, and rubella. In addition, we are now able to predict with some certainty the year-to-year changes in the influenza virus and design a protective flu vaccine.

However, worldwide, the toll of human life and suffering brought by other infectious diseases, such as malaria, filariasis, schistosomiasis, and hepatitis, remains staggering. In the United States, influenza and pneumonia continue to affect millions of people and are still the sixth leading cause of death; measles and tuberculosis are re-emerging; and Hemophilus influenza B and Group B streptococcus cause permanent disability in thousands of young children each year. In addition, newly recognized diseases are sweeping in to challenge us--Lyme disease, Legionnaire's disease, and--most recently and most devastating--the AIDS pandemic.

We at NIAID look to the decade of the 1990s with enthusiasm, energy, and resolve. I am confident that we can meet the challenges of the 1990s through the knowledge that we have gained and will continue to gain through investments in basic and clinical research. Such is the nature of biomedical research. Its dividends may be unpredictable, but they are inevitable.

Mr. Chairman, the FY 1991 budget request for this Institute is $886,875,000. I will be pleased to answer any questions you may have.

BIOGRAPHY OF DR. ANTHONY S. FAUCI

December 24, 1940. Brooklyn, New York

Education:

College of Holy Cross, 1962 - A.B.; Cornell University Medical College, 1966 - M.D.

Professional History:

1966-1967, Intern, Department of Medicine, New York Hospital-Cornell Medical Center. 1967-1968, Assistant Resident, Department of Medicine, The New York Hospital-Cornell Medical Center. 1968-1970, Clinical Associate, Laboratory of Clinical Investigation, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Bethesda, Maryland. 1970-1971, Senior Staff Fellow, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1971-1972, Chief Resident, Department of Medicine, New York Hospital-Cornell Medical Center; Instructor in Medicine, Cornell Medical College. 1972-1974, Senior Investigator, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1972-present, Consultant in Infectious Diseases, The National Naval Medical Center, Bethesda, Maryland. 1974-1980, Head, Clinical Physiology Section, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1977-1984, Deputy Clinical Director, NIAID, NIH, Bethesda, Maryland. 1980-present, Chief, Laboratory of Immunoregulation, NIAID, NIH, Bethesda, Maryland. 1984-1988, Clinical Professor, Department of Medicine, Division of Rheumatology, Immunology, and Allergy, Georgetown University School of Medicine, Washington, D.C. 1985-1988, Clinical Professor, George Washington University School of Medicine and Health Sciences, Washington, D.C. 1984-present, Director, NIAID, NIH, Bethesda, Maryland. 1988-present, Director, Office of AIDS Research, NIH, and Associate Director of NIH for AIDS Research, Bethesda, Maryland.

Board Certification and Military Service:

American Board of Internal Medicine-June 21, 1972. American Board of Allergy and Immunology-March 1, 1974. American Board of Infectious Diseases-October 15, 1974. U.S. Public Health Service, July 1968-June 1970; July 1972-Present.

Professional Organizations:

American Federation for Clinical Research, American Association for the Advancement of Science, American Association of Immunologists, American

Medical Association, Fellow of the American Academy of Allergy, Infectious Diseases Society of America, American Society for Clinical Investigation, Fellow of The American College of Physicians, Association of American Physicians, Collegium Internationale Allergologicum, Charter Member of the Clinical Immunology Society. The Institute of Medicine of the National Academy of Sciences (USA).

Offices Held:

Councillor, Eastern Section, American Federation for Clinical Research (AFCR), 1977. National Councillor, AFCR, 1978-1979. President, AFCR, 1980-1981. Recorder, Association of American Physicians, 1988-present.

Advisory Boards and Committees:

Chairman, Allergy and Immunology Committee, MKSAP V, American College of Physicians. Advisory Panel, The American Board of Medical Laboratory Immunology. Member, Committee on Clinical Immunology and Immunopathology, American Association of Immunologists, 1980-1985. Representative of American Association of Immunologists to the Examinations Committee of the American Board of Allergy and Immunology, 1981-present. Postgraduate Education Committee, American Academy of Allergy, 1979-1982. Member, NIAID Study Group on Immunology, 1980. Member, Section of Physiology in Clinical Science of the American Physiological Society, 1980-1984. Member, Subcommittee on the Classification of Vasculitis, American Rheumatism Association 1980-present. Ad Hoc Committee, The National Foundation for Infectious Diseases, 1980-present. Subcommittee on Clinical Sciences, Publications Committee, American Physiological Society, 1980-1984. American Association of Immunologists, 1982-1985. Member, NIAID Working Group for AIDS, 1982-present. Member, American Federation for Clinical Research President's Public Policy Advisory Committee, 1983-present. Board of Directors, American Board of Allergy and Immunology, 1984-1987. Participant in the USA - People's Republic of China Immunology Cooperative Agreement, August 10-22, 1983, Beijing and Shanghai, PRC. Member, Scientific Advisory Board, Medical Biology Institute, La Jolla, CA, 1983-1984. Participant in the USA-Japan Eye Immunology Advisory Conference, November 27 to December 1, 1983, Honolulu, HI. Member, External Advisory Committee, Multipurpose Arthritis Center, Duke University Medical Center, 1984-present. Member, Honorary Advisory Board, Italian-American Medical Association, 1984-present. Member, Peripatetic Club, 1984-present. Ex Officio Member, National Diabetes Advisory Board, 1984-present. Ex Officio Member, National Digestive Diseases Advisory Board, 1984-present. Chairman, Search Committee for Director, National Institute of Child Health and Human Development, 1985. Member, Department of Health and Human Services Task Force on Alzheimer's Diseases. The Albert Lasker Medical Research Award Jury, 1985-present. Deputy Ethics Counselor, Department of Health and Human Services, 1985-present. Member, Department of Health and Humans Services Committee to Coordinate Environmental and Related Programs, 1985-present. Member, Scientific Organizing Committee, Joint Meeting of the Italian Society of Immunology and Immunopathology-National Institutes of Health on "Human Lymphocyte Activation," Florence, Italy, September 5-7, 1985. Member, United States Delegation to the United States-Japan Cooperative Medical Science Committee, 1985-present. Member, U.S. Public Health Service AIDS Executive Task Force, 1985-present. Chairman, NIH AIDS Executive Task Force, 1985-present. Coordinator, NIH AIDS Research, 1985-present. Member, Scientific Seminar Subcommittee, National Institutes of Health Centennial Program, 1985-1987. Member, Advisory Board, Clinical Immunology Newsletter, 1986-1988. Member, Scientific Organizing Committee, International Conference on Lymphocyte Activation and Immune Regulation, Newport Beach, CA, February 28-March 2, 1986. Member, Planning Committee, Clinical Immunology Society, 1986. Member, International Advisory Committee, International Conference on AIDS, Paris, France, June 23-25, 1986. Member, Advisory Group, Institut Scientifique Roussel-Uclaf, 1987-1989. Ex Officio Member, National Kidney and Urologic Diseases Advisory Board, 1987-present. Member, International Programme Committee, 8th International Congress of Immunology, Budapest, Hungary, 1987. Member, International Advisory Committee, IVth International Conference on AIDS, Stockholm, Sweden, June 12-16, 1988. Member, NIH Resource Allocation Group, 1987-1989. Member, Committee for the Coordination of Research Programs on the Acquired Immunodeficiency Syndrome of the Ministry of

Health of Italy, 1988-present. Institute of Medicine Roundtable for the Development of Drugs and Vaccines Against AIDS, January 17, 1989, through December 31, 1991.

Editorial Boards:

Dr. Fauci has been or is on the Editorial Board of 27 scientific journals in the field of immunology, allergy and infectious diseases. These include: The Journal of Clinical Investigation, The Journal of Immunology, Journal of Infectious Diseases, Journal of Clinical Immunology. Dr. Fauci is also the Editor of one of the major textbooks of medicine in the world, "Harrison's Principles of Internal Medicine."

Awards and Honors:

Alpha Omega Alpha. Kileen Prize for Excellence in Chemistry (College of the Holy Cross). John Metcalfe Polk Prize for General Efficiency (Cornell University Medical College). Alfred Mortitz Michaelis Prize for Efficiency in General Medicine (Cornell University Medical College). U.S. Public Health Service Meritorious Service Award, 1979. Arthur S. Flemming Award, 1979 - Given to the 10 outstanding employees in the U.S. Federal Government. Squibb Award of the Infectious Diseases Society of America, 1983. U.S. Public Health Service Distinguished Service Medal, 1984. Food and Drug Administration Commissioner's Special Citation, 1984. 1985 Citation Classics (Current Contents) for article - A.S. Fauci, D.C. Dale, and J.E. Balow: Glucocorticosteroid therapy: mechanisms of action and clinical considerations. Ann. Intern. Med. 84: 304-315, 1976. Who's Who in America, 44th Edition. Who's Who in Science and Technology, 2nd Edition. 1985 Stanford University Center Survey of the American Rheumatism Association membership ranked the work of Dr. Anthony S. Fauci on the treatment of polyarteritis nodosa and Wegener's granulomatosis as one of the most important advances in patient management in rheumatology over the past 20 years. The Clemens von Pirquet Award of Georgetown University Medical Center, 1986. Doctor of Science, Honoris Causa, College of the Holy Cross, Worcester, MA May 29, 1987. The Kober Lecture Award of the Association of American Physicians, 1988. Public Health Leader of the Year Award of the Commissioned Officers Association of the U.S. Public Health Service, 1988. The National Institutes of Health Clinical Center Annual Distinguished Clinical Educator Award, 1988. 1988 Citation Classics (Current Contents) for article - A. S. Fauci, B. F. Haynes, P. Katz: The spectrum of vasculitis. Ann. Intern. Med. 89: 660-676, 1978. The Leadership Award of the Columbus Citizens Foundation, Inc., for "Inspired Leadership and Outstanding Achievement in the Field of Medical Research," New York, NY October 8, 1988. American Association for the Advancement of Science/Westinghouse Award for Public Understanding of Science and Technology, 1988. The National Hemophilia Foundation Special Award for Research in AIDS, 1989. The Lee P. Brown National Public Service Award of 1989 presented by the National Academy of Public Administration and the National Society for Public Administration. The Duke University Award for Rheumatologic and Immunologic Research, 1989. The William Beaumont Award of the American Medical Association, 1989. The academic Excellence Award from Children's Hospital National Medical Center, Washington, DC, 1989. The Surgeon General's Exemplary Service Medal, 1989. The Surgeon General's Medallion, 1989. The 1989 Achievement Award of the American Association of Physicians for Human Rights. The 1989 National Medical Research Award of the National Health Council. The Flame of Hope Award of the Terri Gotthelf Lupus Research Institute, November 2, 1989. The 1989 Maxwell Finland Award in Infectious Disease presented by the National Foundation for Infectious Diseases. The 1989 Helen Hayes Award for Medical Research. Visiting Professor of Medicine at a large number of major medical schools throughout the country.

Publications:

Dr. Fauci has authored over 680 scientific publications in the field of basic and clinical immunology and infectious diseases.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. Dr. Fauci, thank you very much for your statement.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

AIDS VACCINES

Question. Dr. Fauci, I understand we are in phase I trials to test an AIDS vaccine in monkeys. Early results indicated that vaccine development is clearly feasible. If such a vaccine were developed and proven safe and effective for humans, and fully licensed by FDA, what category of people should most appropriately be vaccinated?

Answer. Several high-risk groups would be advised to take a vaccine for human immunodeficiency virus (HIV). In the U.S. these groups would include various types of health care workers, such as surgeons, emergency room personnel, phlebotomists, general nurses, laboratory workers, and dentists; other people whose work takes place under emergency circumstances, such as police and firemen; homosexual and bisexual men practicing high-risk behaviors; users of intravenous drugs; and research laboratory personnel working with HIV. Additionally, a vaccine would be especially important in areas of the world where the AIDS epidemic is spreading rapidly within the general population, such as Haiti and central Africa.

Question. How many years do you believe it will be before we have an AIDS vaccine for humans?

Answer. Scientists developing a vaccine for HIV infection must first complete additional studies in animals. This research is necessary to develop an understanding of how these exciting, potential vaccines protect test animals from becoming infected with organisms that are highly similar to HIV. These studies are critical to the translation of results in animal research to a product that will be safe and efficacious in people. Then, much work remains in testing a candidate vaccine in people, including phase I, II, and III clinical trials, each of which will take several years to complete. It is conceivable that a vaccine would be generally available within this decade.

AIDS DRUGS

Question. The Committee received a summary briefing on the AIDS situation from Dr. Mason. We were told that there are 34 AIDS drugs in clinical trials. I understand that 10,000 people are involved in these trials in 47 sites across the country including 15 pediatric sites. Which of these several drugs shows the greatest promise for early and effective use on a wide scale basis?

Answer. The need for more effective and less toxic agents to treat HIV infection is clear. Several new agents currently under investigation show preliminary evidence of being less toxic to bone marrow cells than AZT, an attribute that may prove to benefit patients who cannot tolerate the drug. These drugs may prove to be safe and effective alone or in varying combinations with each other or with AZT.

This year, four new antiretrovirals entered phase I clinical trials: dideoxyinosine (ddI), N-butyl DNJ, soluble CD4, and dideoxydidehydrothymidine (D4T). These initial studies will help determine the maximum tolerated dose and provide preliminary information on the antiviral effects of the drug as well as its ability to improve the status of the immune system. Researchers have completed a phase I trial of ddI showing a favorable initial response. A trial of dideoxycytidine (ddC) was also completed this year. Because ddC shows promise in limiting the viral replication and has a different toxicity profile than AZT, studies are comparing alternating regimens of AZT and ddC. Study of soluble CD4 is another promising area of research. This molecule serves as the receptor for HIV on human cells and by blocking the receptor we may be able to prevent the virus from gaining entry into the cell. Laboratory studies are encouraging, and in a clinical trial, the drug appears to be well tolerated and may be beneficial, although the efficacy has yet to be determined.

We are also studying the drug probenecid, a widely used drug with very low toxicity, which may enable the body to use AZT more efficiently. A recent AIDS Clinical Trials Group (ACTG) sponsored study showed that probenecid was highly effective reducing the metabolic clearance of AZT, raising the possibility that probenecid may be effective in reducing the daily dose of AZT required to treat HIV-infected patients. This capability has the potential to improve convenience and compliance.

The ACTG will continue to test promising new therapies as they become eligible for clinical research. The considerable number of new potential antiviral drugs is highly promising and should significantly expand the repertoire of available therapies for treating HIV infection. As treatment options increase, scientists will be able to develop optimal therapies for people in varying stages of HIV disease.

USE OF AZT

Question. Dr. Fauci, since our hearings last year, two major studies have been concluded, both of which showed that AZT is recommended for use in those with the HIV infection but who have not yet developed AIDS. I understand that the recommended procedure is that HIV positive individuals should be given AZT when their T-cell level drops below a certain point. We are told that there are an estimated 300 to 400 thousand people who would fall into this category. It seems to me that it is more important than ever to have a wide-spread and confidential testing program in place as those who are now HIV positive can be helped. In your opinion, Dr. Fauci, do we have all the confidentiality safeguards now in place to permit and encourage a wide-spread testing for HIV infection?

Answer. From a national perspective, no, we do not have all the confidentiality safeguards now in place to enable wide-spread testing for HIV infection. We cannot safeguard confidentiality across the country because the control, coordination, and policy setting for HIV confidentiality testing occurs at state and local levels.

PEDIATRIC AIDS

Question. I understand that the traditional procedure was to test a drug for adults, take it through the entire process to FDA approval, and then begin the process all over again for children. We are now simultaneously testing many of these AIDS drugs both for adults and children. Of the 34 drugs now in clinical trials, how many of these are also being tested for use with children?

Answer. There are currently 42 drugs and drug combinations in HIV clinical trials. Several distinct drugs as well as a number of drug combinations are being tested in children with HIV infection, including AZT, intravenous immune globulin (IVIG), dideoxyinosine (ddI), and aerosolized pentamidine. Protocols are in development for hyperimmune anti-HIV IVIG, dideoxycytidine (ddC), and recombinant CD4. Many drugs that are tested in adults are not being studied in children because of the much smaller number of children infected which means fewer potential candidates for study, and therefore, a lower likelihood of a successful study.

The recent expansion of pediatric clinical trials for HIV-infected children has allowed more drugs and studies to become available to these children than has been true in the past. The expansion has also enabled researchers to begin phase II and III trials in children. The NIAID is again expanding its pediatric effort, which should have another impact on the numbers of children who will have access to HIV clinical trials.

Question. Is this occurring, to your knowledge, with drugs for any other diseases? Should it be?

Answer. NIAID tests drugs and vaccines as a part its research in microbiology and infectious diseases, and clinical trials in the pediatric population are required to evaluate new products that are designed to treat or prevent childhood infections. Our clinical trials procedures conform fully to FDA guidelines, including testing new products for safety and efficacy in adults before they are studied in children. For infections that occur predominantly in the pediatric population, however, it may not be possible to determine efficacy of a new drug or vaccine in adults. In these cases, clinical trials are conducted in children only after safety of the drug or vaccine has been demonstrated conclusively in adults.

Testing new drugs and vaccines in children should proceed only after the welfare of children has been assured. Whenever possible, testing should be done first in adults who are capable of making their own informed decision to participate in clinical trials and who can communicate directly with medical staff about the effects of a new treatment, including the occurrence of untoward side effects. In situations where efficacy can not be demonstrated in adults because the condition occurs only in children, clinical trials should be considered in the pediatric population after the safety of the drug or vaccine has been shown in adults.

ASTHMA

Question. Dr. Fauci, I understand that we had a significant increase in the incidence of hospitalization and deaths due to asthma. This has occurred particularly in inner-city areas with minority groups. What can you tell the Committee about the upswing in asthma cases?

Answer. The past decade has witnessed not only an increase in the prevalence of asthma in the inner city, but some data suggest that the mortality rate may be increasing among inner city African Americans and Hispanics as well. These changes have been attributed to a variety of factors ranging from adverse environmental exposures, such as increased pollution, to inaccessibility to health care due to socio-economic inequities.

For this reason we have launched a National Cooperative Inner City Asthma Study which is designed to identify and elucidate precisely what factors are responsible for the increasing morbidity and mortality in these populations followed by a structured therapeutic intervention aimed at reducing or eliminating these factors in the study population. It is also anticipated that this will provide information upon which future interventions can be designed.

LYME DISEASE

Question. I understand that a major roadblock to the effective treatment of Lyme disease has been the lack of reliable tests to diagnose the disease during early stages of infection. I recently read a report that a new test called PCR which was developed by your scientists will make it easier to more accurately diagnose Lyme disease. Can you tell us about this test and its impact on studying this and other diseases?

Answer. The PCR test is a state-of-the-art approach to increasing the sensitivity with which the presence of specific genetic material can be detected. This technique has broad applications from DNA fingerprint analyses that can be used in criminal cases to the detection of the presence of a specific infectious agent such as the bacterium that causes Lyme disease or the Human Immunodeficiency Virus in individuals concerned about the possibility of contracting AIDS. This is a very powerful technique that theoretically would enable a lab technologist to detect the presence of a single organism or virus in a clinical sample.

Researchers at the NIAID Rocky Mountain Laboratories have reported the development of a PCR test for the Lyme disease spirochete. Similar developments are in progress at several other U.S. laboratories. These are very exciting developments. However, it should be realized that at present this technology is not ready for general application in diagnostic laboratories for several reasons. First, establishment of PCR in clinical laboratories requires rigorous procedures to ensure that clinical samples are not contaminated thus creating a problem with false positive test results. In order to avoid contamination problems, special measures would have to be adopted to ensure that PCR materials are isolated from the area in which clinical samples are handled. Second, PCR requires the purchase of new equipment and extensive training of personnel. Third, this test, even when ready for general use, will probably remain as a backup for faster, cheaper and less complicated serological tests. Lastly, PCR for Lyme disease tests is still in the developmental stage requiring further refinement before they can be viewed as reliable diagnostic tests for Lyme disease.

FETAL TISSUE AND AIDS TREATMENT

Question. Dr. Fauci, in an October 1989 speech you discussed the theoretical possibility of using fetal cells to reconstitute the immune system of AIDS patients. Unlike adult cell transplantations, fetal cells would not provoke tissue rejection problems. Attempts to reconstitute the immune system of AIDS patients using bone marrow transplants from the patient's identical twin have not been successful. The Department of Health and Human Services has continued to ban any Federal funding of transplantation research using fetal tissue from induced abortion. To your knowledge is any foreign research being considered using fetal cells to reconstitute the immune systems of AIDS patients in order to get around the U.S. ban?

Answer. The NIAID is not sponsoring any foreign research using fetal cells. Neither do we have any initiatives that plan to conduct such activities.

ENROLLMENT OF WOMEN IN NIAID-FUNDED CLINICAL TRIALS

Question. The General Accounting Office is conducting an investigation to determine the extent to which women are excluded as subjects from clinical trials. In 1987 NIH implemented a new policy that requires researchers to provide a rationale if they plan on excluding women from a study. The GAO report will be evaluating the effect of the new policy on the inclusion of women in study populations. Many medical treatments used on women are based on research which was conducted entirely on male subjects. Women with AIDS are being excluded from clinical trials because they do not develop the same opportunistic infections as men. What is NIAID's policy on the enrollment of patients in clinical trials?

Answer. The NIAID's policy is to offer enrollment in its clinical trials to all eligible parties. People are excluded from the studies only when there are specific scientific or safety criteria necessitating an exclusion. There are never arbitrary exclusions on the basis of sex.

Question. To what extent are women excluded as patients?

Answer. Women are not excluded, and are in fact well represented, in the NIAID clinical trials system. They participate in the studies to a higher degree than their rates of HIV infection. Ten percent of U.S. AIDS cases are in women, compared to 11 percent of patient enrollment in the NIAID clinical trials system. Women are not excluded in any of the studies and some studies specifically address the needs of HIV-infected women.

Clinical trials that include women are particularly important because the number of women developing AIDS is increasing dramatically. Many HIV-infected women are of minority background. The NIAID is using several means to increase the participation of minority populations in the clinical trials. A new Request for Application (RFA) under development, entitled "The Expansion of the AIDS Clinical Trial Group to Underrepresented Minorities," is expected to appear in the NIH guide early this year with the first awards anticipated for the Fall of 1990. Recognizing the importance of collecting data that includes minorities, we are working to increase minority participation in our studies through this RFA by several means, for example, by including provisions for bringing the necessary social services to potential minority participants. Although we are making progress in recruiting minorities into the system, we have strengthened our resolve to increase minority representation even further in our studies.

The pediatric clinical trials units are also being expanded. This expansion includes the establishment of perinatal centers serving women in at-risk populations. This feature will provide for increased attention given to pregnant HIV-infected women and their children in AIDS clinical trials.

A critical goal of HIV treatment research is to halt the transmission of HIV from an infected mother to her baby. The ACTG is sponsoring several studies using AZT in both newborns and pregnant women to try to block this form of HIV transmission. These studies are now getting underway. We have begun the first clinical trial of AZT in pregnant women, a vital first step toward determining whether AZT given during pregnancy can prevent mother-to-baby transmission of HIV.

Question. What progress has been made in identifying gender differences in disease etiology, course, and treatment?

Answer. Differences in disease outcome are almost exclusively correlated to socio-economic factors as well as other health associated risk factors, such as drug use. The HIV-infected poor and people with other health risk factors have a worse prognosis than people who are nondrug-using and middle class. The prognosis is also different in children, in whom HIV infection follows a different course from that in adults. Differences in disease outcome based on sex, race, or other factors have not been documented. However, several epidemiologic studies are gathering more detailed information on possible subtle differences, as yet unknown, that may exist in the course of HIV infection in various populations.

Regarding the course of the AIDS epidemic, the spread of the epidemic to the heterosexual population is affecting women much more acutely than men. Women appear to be more susceptible to this form of transmission than are men, and those affected are predominantly from lower socio-economic classes and minorities. The needs of HIV-infected women are being addressed in the NIAID clinical trials system through several mechanisms designed to increase the participation of minority populations in the clinical trials. A new RFA under development, entitled "The Expansion of the AIDS Clinical Trial Group to Underrepresented Minorities," is expected to appear in the NIH guide early this year with the first awards anticipated for the Fall of 1990. Recognizing the importance of collecting data that includes minorities, we are working to increase minority participation in our studies through this RFA by several means, for example, by including provisions for bringing the necessary social services to potential minority participants. Although we are making progress in recruiting minorities into the system, we have strengthened our resolve to increase minority representation even further in our studies.

MYCOPLASMA-ASSOCIATED AIDS ILLNESS

Question. Shyh-Ching Lo and colleagues at the Armed Forces Institute of Pathology have identified a new human pathogen which is associated with fatal disease in AIDS patients and others without AIDS. The mycoplasma may cause some of the serious conditions afflicting AIDS patients, and could be a possible cofactor in the progression of AIDS after infection with HIV (human immunodeficiency virus). Co-factors may explain why some infected with HIV become sick more quickly than others. The mycoplasma is potentially treatable with common antibiotics. What is the status of studies involving the microbe Mycoplasma incognitus, discovered by researchers at the Armed Forces Institute of Pathology?

Answer. A special meeting is being held on March 6 to address the state of knowledge about this microbe as well as possible priorities for clinical and basic research. Both basic and clinical scientists from the NIAID, the Armed Forces Institute of Pathology, and the NIH clinical center will review data about Mycoplasma incognitus. This review will serve as a basis for assessing whether sufficient knowledge is available for diagnosing possible disease states caused by the organism, developing diagnostic tools, and determining what are the next logical steps to take to address the potential implications of this new discovery as well as important research areas. Basic research will ensue in the study of this organism, and based on the outcome of the meeting, it is possible that clinical studies may also follow.

CENTERS FOR AIDS RESEARCH

Question. In FY 1988 NIAID established multidisciplinary Centers for AIDS Research at seven universities and plans to award the centers grants for five years. Funding for the first year was set at $6.7 million. The centers are at Purdue University; University of California campuses at Davis and San Francisco; University of Washington, Seattle; University of Alabama, Birmingham; Stanford University; and Albert Einstein College of Medicine. What is the progress of research at the Centers for AIDS Research which were established in FY 88?

Answer. The Centers for AIDS Research (CFARs) provide shared core research facilities to facilitate and accelerate AIDS and AIDS-related research. Through CFAR funding, a variety of activities that are difficult or impossible to support through the traditional mechanisms of grant funding, i.e., core facilities, alterations and renovations, and developmental funding are accomplished.

The CFARs provide strong leadership in facilitating creative, interactive AIDS research activities among a variety of laboratory and clinical investigators. The CFARs are recognized as a major element in the parent institution's organizational structure, and each CFAR director receives a firm commitment from the institution to provide necessary personnel, facilities and space for research projects. Laboratory and clinical equipment or services are shared by a number of investigators engaged in AIDS research. Funds are available for upgrading laboratories and providing proper containment facilities for working with HIV and related retroviruses. CFAR funds are also available to support salaries and research costs both for new investigators at the parent institution who have not previously received major grants or contracts, and for investigators newly recruited to the institution.

The CFARs collectively cover a wide range of scientific areas. The Purdue CFAR generates peptides for use by scientific investigators and has a mass spectrophotometry facility. The University of California, Davis, CFAR does molecular cloning; generates probes, synthetic oligonucleotides, and expression vector systems, and performs DNA sequencing. They also have a transgenic facility. The University of Washington CFAR has available five research core groups: retrovirology, immunology, primate research, biostatistics/epidemiology, and clinical research. The University of Alabama CFAR has expanded its number of research programs to include both pediatric and adult experimental therapeutic research. At present, fifteen clinical protocols are being conducted in adults. The Stanford University CFAR is providing new laboratory and clinical facilities, which are due to be completed in March 1990. In addition, an AIDS outpatient clinic will be completed in October 1990. The Albert Einstein College of Medicine CFAR has a flow cytometry facility to perform immunophenotyping of cells, a hybridoma facility to produce monoclonal antibodies, and a nucleic acid and peptide facility to sequence genes and generate peptides. The University of California, San Francisco, CFAR provides a data management core, an AIDS specimen bank, and a facility to assay for AIDS drugs and their metabolites.

NIAID funded seven CFARs in FY 1988. Four additional CFARs were funded in FY 1989, bringing the total to eleven.

CLINICAL TRIAL PROGRAMS

Question. In November 1988 NIAID announced the creation of a new community based clinical trial program. Community physicians and clinics will monitor patients receiving experimental drugs and report the results to NIAID. The Institute intends that the program will offer the benefits of new drugs to minorities and IV drug abusers and encourage greater compliance with clinical trial rules. NIAID has been experiencing recruiting problems for some of its AIDS studies. The Institute is also concerned that many patients are not complying with study protocols by taking other "underground" drugs or by surreptitiously determining whether they are receiving placebo and if they are, dropping out of the study or obtaining drugs such as AZT from other sources. Such actions will obscure the results of the clinical trial. FDA's proposed parallel track would allow patients outside a clinical trial earlier access to experimental drugs. It has been criticized as potentially having an adverse impact on the recruitment of subjects for clinical trials and exposing patients to drugs without a sufficient track record to determine adequate safety and efficacy. Please describe and explain how NIAID's community based clinical trial program is functioning.

Answer. The Community Programs for Clinical Research on the Acquired Immunodeficiency Syndrome (CPCRA) initiates a new level of clinical research on infection with HIV, by extending the opportunity for participation in HIV research activities to community clinicians and their patients. It is designed to expand the population base involved in HIV research as well as to take advantage of the extraordinary expertise which has developed at the community level in the day-to-day management of HIV infected persons. By placing the research priorities and execution in the hands of community-based clinicians, the CPCRA program will enlarge the availability of research opportunities to those who might not have access to the existing university-based NIAID clinical trials system.

This initiative is a pilot project in the delivery of administrative and methodologic support for this research and, at the same time, is designed to provide wider access to experimental therapies for HIV infection and its sequelae. Enabling the participation of community-based clinicians and organizations in clinical research also extends participation in well-designed clinical studies to persons currently underrepresented in NIAID-supported HIV research -- specifically, minorities, sexual partners of HIV-infected persons, and intravenous drug users.

In establishing community-based clinical research programs, the CPCRA will also be forging new methodologies for the conduct of clinical research, incorporating existing methods in new settings, and involving community clinicians in the design and conduct of clinical research projects. These projects may range from the testing of drugs or combinations of drugs/products for treating HIV or its manifestations to projects which are purely observational design or patterns of care type studies.

The CPCRA awardees represent extraordinary geographic, racial and risk group diversity. These programs represent an extraordinary level of access to "hard to reach" groups and a clear commitment of these principal investigators to the service of those patient populations currently underrepresented in HIV research.

Question. What AIDS drugs are being evaluated in the community based clinical trial program?

Answer. This program was just funded, and three protocols are soon to be activated for study by the CPCRA. The community clinicians and Principal Investigators of the CPCRA have decided the most appropriate first work of the group should be the development and implementation of the following studies:

- A study comparing two widely used agents for the prevention of toxoplasma gongii encephalitis in persons with HIV infection. Toxoplasma encephalitis is an opportunistic infection which frequently occurs in persons with late stage HIV infection which may be prevented or delayed with appropriate prophylaxis.

- A study of the comparative efficacy of ddI versus ddC in patients with HIV who are intolerant to or have failed AZT therapy.

- An observational database project which will assist community clinicians in regular assessment of clinical and therapeutic patterns among all their patients as well as the potential to answer important questions about changing patterns of HIV disease and care of persons with HIV infection.

The community clinicians of the CPCRA have self-selected into relevant interest groups from which ideas for multi-site studies will initiate in collaboration with the medical, statistical and methodologic input from NIAID staff. These interest groups are as follows:

- Antiretroviral therapies
- Opportunistic infection prevention and treatment
- Observational database project
- Patient care and special populations/compliance

Question. Do you anticipate that the community-based clinical trial program will have an effect on AIDS patients who do not comply with trial protocols?

Answer. Patients enrolled in clinical trials under the community program will work closely with the primary care physicians. This arrangement is expected to lead to very good compliance rates within the CPCRA.

Question. What is your opinion of the impact FDA's proposed parallel track program could have on an AIDS clinical trial?

Answer. There are two major potential adverse affects on clinical trials which could occur as a result of proceeding with the parallel track. The first is that subjects will stop participating in clinical trials and merely opt to take drugs which are available on the parallel track. The second is that the additional burden in cost and administration of parallel track would deter pharmaceutical firms from pursuing development of potential drugs to treat HIV infection or its complications. The following will discuss each of these in slightly more detail.

The first concern is that patient accrual to clinical trials will be impaired. The concern is very simply that patients, if given a choice between parallel track drug administered by their personal physician and clinical trials studying a given agent, will choose parallel track. This concern is expressed most often by investigators involved in the studies and by members of the pharmaceutical industry. It is a somewhat difficult issue to address since it is largely speculative. It certainly is conceivable that this would be the case. However, it is important to point out that there are many more patients with HIV infection than any feasible or imaginable clinical trial system could accommodate. Furthermore, drug development and clinical trials of new agents or interventions succeed even though there are readily available alternative treatments, many of them commercially available and known to be effective. While this is a valid concern, the NIH believes that there are more than enough patients at this point in time to fill the clinical trials of high priority which need to be done, and that in fact the parallel track stands at least as good a chance of improving our studies and the data from them because the patients who participate will be genuinely interested in participating in research and not coerced to do so in order to gain access to a "life saving drug."

The second major concern relates to the additional burden of parallel track on pharmaceutical sponsors and the fear that this burden will keep them out of the arena of drug development for HIV infection and its complications. It is very well known that the costs associated with the clinical development and licensing of a new drug are enormous. Distribution of drugs through the parallel track will add a significant burden and expense to the development of a given drug. Most of this expense is associated with the distribution mechanism, investigational drug tracking, and data collection associated with parallel track. These expenses associated with data collection and the implementation of a distribution and tracking system are significant and could, in at least some instances, sufficiently raise the perception of risk of investment on the part of some pharmaceutical firms that they would elect to pursue drug development and investment of their resources in less risky alternatives. This particular concern is impossible to address, although it is clear that the costs associated with the prototype distribution of ddI are quite large and of considerable concern to Bristol Myers. On the other hand it is extremely likely that as more treatments become available this concern will lessen. It is also clear that some small pharmaceutical firms cannot handle this additional cost of drug development. Finally, another concern over liability will possibly become important.

At the present time, over 9,700 patients have been accrued into NIAID-sponsored clinical trials. Of these, 58 studies are ongoing and accruing patients and another 48 have either completed accruing patients or are completed. These clinical trials are studying 42 different single agents or combinations of agents for the entire gamut of conditions affecting patients with HIV infection. Because treatment INDs are held by individual sponsors it is uncertain exactly how many patients are currently enrolled in all of the AIDS treatment INDs. However, some related data are available from the experience from ddI. Over 600 patients have been enrolled in the ddI clinical trials since they were opened just over three months ago. Approximately 6,000 patients, according to Bristol Myers, have received the drug outside of the clinical trials. It is important to note that the accrual for the clinical trials is proceeding at a pace which is as good as or better than the accrual rate to other studies in the NIAID's AIDS clinical trials history, and that the rate of accrual continues to increase.

The number of additional patients who could reasonably be expected to participate if the parallel track is pursued is almost impossible to estimate. The answer is entirely dependent upon the success of drug development as it proceeds and upon the particular conditions related to HIV for which drug development is successful. The more successful we are at developing potentially promising drugs and the more frequent the particular condition, the greater the number of patients. In this regard it is very important to point out that clinical trials, in all but the most unusual conditions, rarely enroll more than a small minority of the patient population; this is true for all diseases, whether related to HIV or not.

AIDS CLINICAL TRIAL INFORMATION DISSEMINATION

Question. The purpose of the AIDS Clinical Trials Information Dissemination program is to make information on AIDS clinical trials and their results available to physicians, clinics, patients, advocacy groups, state and local health agencies, Congressional and Executive offices, and the media. NIAID has been experiencing recruiting problems for some of its AIDS studies. The Institute is also concerned that many patients are not complying with the study protocols by taking other "underground" drugs or by surreptitiously determining whether they are receiving placebo and if they are, dropping out of the study or obtaining drugs such as AZT from other sources. Such actions will obscure the results of the clinical trial. What is the status of the AIDS Clinical Trials Information Dissemination program?

Answer. The AIDS Clinical Trials Information Service (ACTIS), opened in May 1989, provides a central resource for disseminating information on NIH- and industry-sponsored clinical trials of new therapies for people infected with HIV. This service is free to users and is jointly sponsored by NIAID and the FDA in collaboration with the CDC and the National Library of Medicine.

By calling a toll-free number, 1-800-TRIALS-A, callers speak to trained health specialists, who provide information about AIDS clinical trials. These specialists access a database featuring up-to-date, accurate information on studies currently underway. They provide information on the purpose of study protocols, studies that are open to patient accrual, study locations, eligibility requirements and exclusion criteria, and names and telephone numbers of contact persons.

After having been open for only three days, the Service expanded its number of specialists and incoming lines, due to an overwhelming response from the public. Shortly thereafter, data from the FDA database on industry-sponsored efficacy trials for HIV were added to the AIDS Clinical Trials Information Service database. The protocol database contains 231 records, 146 of which are supplied by NIH and 85 by FDA. Managed by the National Library of Medicine, the database has up-to-date medical search terms enabling health professionals and others to search the database for specific medical topics.

During January 1990, the ACTIS responded to 50 percent more calls than in the previous month, a total of 1,821 calls. To date, the service has answered over 17,000 calls from every state in the country. Over half of these calls have been from patients and their families, and slightly less than 25 percent are from doctors and other health professionals.

Question. Do you anticipate that such a program will have any effect on patients who are not complying with protocols in AIDS clinical trials?

Answer. The AIDS Clinical Trials Information Service (ACTIS) serves an important educational role, bringing information about clinical trials for HIV infected people to the public. The service should increase the level of knowledge about the clinical trials process in the general public, a process that should enhance understanding of the goals of clinical trials research as well as the significance of individual participation. Because people will enter clinical trials better informed, it is hoped that their compliance will be improved.

TRANSFUSION-RELATED HEPATITIS C

Question. Hepatitis C is the most important complication of blood transfusion; over 150,000 infections occur in the United States each year. Half of those infected will develop chronic liver disease, and 15,000 will develop cirrhosis. Approximately 25,000 Americans die each year of chronic liver disease and cirrhosis, the ninth-leading cause of death in the U.S. An estimated 1 percent of Americans, or 2 million people, are infected with the virus. The viral agent of hepatitis C was identified due in large measure to a NIAID grant funded through the Small Business Innovation Research program. Recently researchers have reported that one form of interferon is beneficial to treating patients with hepatitis C. What is the status of the development of a diagnostic test which will be used to screen donated blood for infection with hepatitis C virus?

Answer. A diagnostic test to detect antibody to an internal protein of hepatitis C virus has been developed. Evaluation of its specificity and sensitivity has been completed. The results look promising and licensure in this country may occur soon. This same test has already been licensed in other countries. Another diagnostic test based on the same antibody/antigen but having a different configuration is currently being tested.

As with other early tests this one in all likelihood will not be the optimal one. Tests based on other viral antibodies such as those made against surface antigens should be developed. A test for the presence of the virus is a "gold standard." Such work is in an early stage of development but may prove difficult since the virus is present only in small amounts in the blood.

SMALL BUSINESS INNOVATION RESEARCH

Question: Has the Small Business Innovation Research program, which funded a majority of the work on the diagnostic test for hepatitis C, been involved in any other research advances at NIAID?

Answer: One excellent example is the development of vaccines for parainfluenza viruses, a group of important respiratory pathogens. Through the Small Business Innovation Research (SBIR) program, one company is now developing a vaccine against Parainfluenza Type I and another has made a vaccine against Parainfluenza Type II. The Type II vaccine is now being considered for human clinical trials, and some large pharmaceutical companies have already expressed interest in manufacturing it.

Another project, funded through an SBIR contract has successfully used recombinant DNA technology to eliminate the adverse reaction encountered in traditional pertussis (whooping cough) vaccines. The investigator found that the negative effects of the pertussis toxin resides in one of its components, which, if properly cloned, can be used for the direct development of a newer, safer pertussis vaccine. This new generation of genetically engineered vaccines promises to be both economical, highly specific against the virulent organism, as well as efficacious.

Other ongoing projects funded under the SBIR program which hold great promise are projects that study the immunological aspects of AIDS-related synthetic peptides, genetic engineering of anti-malarial vaccines and the development of monoclonal methods for the quick and facile diagnosis of Epstein-Barr virus, human fungal pathogens and human papilloma virus.

Question. What is the status of treatment research on hepatitis C?

Answer. Research into the treatment of hepatitis C has progressed to the stage of evaluating drugs that are already available for other viral infections. Liver function became normal with treatment of alpha interferon in over half of the patients. However, relapse, an indication of ineffective treatment, occurred in over half of the patients who had responded favorably initially. A recent study with ribavirin, a licensed broad spectrum oral antiviral drug, indicated approximately the same level of efficacy as alpha interferon.

A rational treatment research program to develop new drugs designed for hepatitis C will require continued basic research to characterize the virus and its replication cycle, to develop model systems for the infection and to learn more about both the pathogenesis and immune response to the disease

TECHNICAL ADVANCES IN IMMUNOLOGY

Question. Dr. Fauci, we have read a lot recently about technologic advances in immunology and molecular biology. Could you please describe for us some of the new opportunities for research within the purview of NIAID that are created because of this new technology?

Answer: Of all fields of biomedical science, immunology was best prepared for the revolution in molecular biology that began about a decade ago. Thus, immunology and molecular biology have both prospered from the natural interaction of the two disciplines. Of the many advances and opportunities in immunology that have been spurred by the experimental approaches of molecular biology, I will mention three:

- Advances in immunology and molecular biology have allowed us to identify and understand the role of hormone-like substances called cytokines which are produced by our immune cells. Cytokines are key regulators of our immune system and their role in health and disease are subjects of intense biomedical research. Cytokines normally appear in trace amounts in the body and, prior to this time, acquisition of sufficient amounts for study or therapeutic uses has been difficult. However, technological advances have lead to the identification of the genes coding these cytokines and have allowed, in the laboratory, the production of cytokines in adequate amounts for research, as well as for pre-clinical and limited clinical trials in treating selected diseases. For example, rGM-CSF, a factor that helps bone marrow generate immune cells, has been used in clinical trials for patients with bone marrow diseases as well as in combination with AZT for AIDS patients.

- A technical milestone in molecular genetics over the past decade has been the recent development of the polymerase chain reaction or PCR. The procedure's importance lies in its ability to amplify small amounts of DNA or RNA (building blocks of our genetic code) more than a million fold in a few hours and analyze it for the presence or absence of specific genetic information. This can now be done on samples too minute for previous standard methods in a far more sensitive and rapid manner. An excellent example of the use of PCR for evaluation purposes, is the detection of genes from HIV in people who cannot be determined to be HIV-positive by conventional means, such as infants born to infected mothers or seronegative, high-risk individuals. Another application of PCR is in exacting analysis of HLA genes and tissue-typing for organ transplantation, and thus, having the capacity to enhance organ matching.

- Over the last decade the use of mouse monoclonal antibodies (mAbs) has been widely employed for basic research, diagnostic, and clinical applications. mAb's have been used alone or linked to drugs, radioisotopes, and toxins in animal and human disease and transplantation studies. Use of such reagents in humans has met with several experimental obstacles including modest biologic activity, side effects, and rapid elimination from the circulation. These problems are mostly due to the fact that the mAb's are raised in mice and are, therefore, recognized as foreign by the human immune system. The recent ability to clone individual genes (human and murine) responsible for immunoglobulin synthesis has led to the generation of genetic constructs that, when inserted into cells, dictate the synthesis of antibody molecules that are part human and part mouse. These "chimeric" human/mouse mAb's are perceived as "less foreign" when used therapeutically, resulting in a lessened immune response against them. Preliminary testing is promising and suggests that "humanized mAb's" will have a wider "therapeutic window" than their murine counterparts.

Question. Dr. Fauci, your institute has the lead in vaccine development in other infectious disease areas in addition to AIDS. Are there any new candidate vaccines that are ready to be tested should additional funds become available?

Answer. Yes, there are several vaccines in the earliest stages of clinical assessment that are ready for expanded clinical trials should additional funds become available.

A new cholera vaccine developed at the University of Maryland Center for Vaccine Development is currently in small-scale phase II clinical trials. This vaccine was developed using recombinant DNA technology, and, as such, it is the first live vaccine to result from this promising new technology to advance to clinical trials. This live, attenuated vaccine is administered orally as a single dose. It promises to be a major improvement in disease prevention technology in less developed areas of the world where cholera is endemic and where health programs can ill afford to burden further an immunization system that relies on disposable needles and syringes, a minimum standard where transmission of HIV is likely to occur.

Initial phase I clinical studies of a new conjugated pneumococcal vaccine that has been developed by NIAID's program will begin within weeks. This vaccine is designed to protect infants and young children from invasive pneumococcal infections, including pneumonia and otitis media. The currently available pneumococcal vaccine is not effective in this very young age group, and the conjugated product is expected to extend protection to this vulnerable age group. If the early phase I and phase II trials are successful, large-scale clinical trials would then be considered for initiation pending availability of funds.

The development of a vaccine to prevent Group B streptococcal (GBS) infections in newborns has rapidly accelerated in recent years. A candidate protein-polysaccharide conjugate vaccine is slated to enter clinical study within the next year. This is very important since GBS causes serious infection and disease in neonates. Approximately 11,000 infants are affected each year, with many deaths and long term disability produced by the infection.

A live, attenuated oral rotavirus vaccine that was developed by NIAID scientists is under study currently in infants in Venezuela. Rotavirus diarrhea is the most serious cause of diarrhea in infants throughout the world, including the U.S., and this vaccine would prevent the most common cause of hospitalization of infants for diarrhea in the U.S. Accelerated efficacy trials of the vaccine could be undertaken with the availability of additional funds.

A glycoprotein D subunit vaccine has been developed against type 2 herpes simplex virus, the etiology of a common sexually-transmitted disease. Other investigators have developed a live attenuated herpes simplex vaccine. Either or both of these vaccines may be useful in immunotherapy of recurrent genital herpes infection and prevention or amelioration of primary infection. The availability of additional funds would permit acceleration of plans to conduct placebo-controlled clinical trials of these new vaccines.

Question. Dr. Fauci, last year, we appropriated funds to double the capacity of your intramural AIDS outpatient clinic. Would you give us a status report on these efforts?

Answer. The newly appropriated funds have been instrumental in permitting NIAID's intramural program to expand its capacity to examine patients in our hospital clinics, diversify our research efforts in evaluating essential therapeutic and preventive treatments for HIV infected patients and implement plans to train health personnel in AIDS clinical research. In March of 1990, the new AIDS research clinic will be open. This expansion of clinical research and care facilities, will enable the intramural program to increase the number of patient visits from 2,600 per year to greater than 5,000 per year. The effect of the expanded facilities will allow the NIAID program to do a larger number of clinical therapy trials. In anticipation of our increased clinical research capacity, we have increased the number of clinical studies being done from 10 to 15 detailed, clinical protocols. The funding is being used to hire more clinical and research skilled health personnel to perform ongoing and planned clinical trials, and to train more physicians in performing clinical AIDS research (AIDS fellowship program).

FLU EPIDEMIC

Question. Dr. Fauci, we are certainly aware that we have had a major flu epidemic this year. What progress on influenza research do you have to report?

Answer. This influenza season was notable for its high percentage of influenza related hospitalizations and deaths, especially in those over the age of 65. During this influenza season an average of 8 percent of all physician visits were due to influenza, and as high as 6.1 percent of all hospitalizations were the result of influenza virus infections. Prevention of influenza virus infection, through vaccination, continues to be the major emphasis of NIAID's research approach for the control of this disease. Research and development of the live, attenuated influenza vaccine, ca vaccine, remains a major commitment of the Influenza Program. Recent studies have suggested that the vaccine might be especially valuable for use in children, a primary source of influenza transmission. In this population, the live, attenuated vaccine appears to afford a longer duration of protection than seen in the inactivated vaccine; is more protective than the inactivated vaccine; and also prevents a virulent type influenza virus from replicating, and therefore spreading to others. Clinical studies have also shown the live, attenuated vaccine to be at least as good as the inactivated vaccine in the general population, although it may not be as good as the inactivated vaccine in the elderly population. The NIAID is currently negotiating a joint research endeavor with a vaccine manufacturer that should accelerate the licensure of the ca vaccine. Interest in improving the inactivated vaccine is also of concern to the NIAID. The Influenza Program is currently evaluating the use of alternative high growth influenza strains for use in the manufacturing of inactivated vaccine. Such strains could provide larger quantities of vaccine, in a shorter amount of time. This would have the advantage of allowing decisions regarding the strain of influenza virus to be used in the subsequent years vaccine to be made at a time when more data was available. Clinical studies to evaluate the use of adjuvants to boost the immune response to inactivated vaccine are also planned. NIAID remains committed to investigate alternative approaches for the control of influenza virus infections, such as the development of antiviral drugs. Amantadine (Symmetrel) is currently the only licensed drug available for the prophylaxis and therapy of influenza A virus infections. The NIAID is continuing the assessment of the therapeutic efficacy of an amantadine analogue, rimantadine, in the treatment of influenza A infections in those patients which are at high risk of developing complications to influenza A virus infection. Thus far, the data are highly suggestive that rimantadine can be effective in reducing the complications often associated with primary influenza virus infections, particularly in the elderly and immunocompromised persons. Rimantadine was previously shown by NIAID supported investigators to be highly efficacious in preventing influenza A infections and did not exhibit the side effects such as nervousness and the inability to concentrate associated with amantadine. An application for licensing of rimantadine for the prophylaxis and treatment of influenza A virus infection was submitted by Hoffmann-La Roche in 1987. This application was reviewed and endorsed by the FDA Advisory Panel. The identification of resistant mutants, a phenomena seen with amantadine as well as antibiotics, has resulted in a delay of licensure. To date, there are no alternative approaches to the control of influenza B infections.

The future of targeted approaches towards the development of antiviral drugs appears promising. NIAID supported basic scientists have made great strides in understanding the complex interactions involved in rendering the influenza virus non-infectious. Research involved in identifying critical structural and chemical moieties necessary for influenza virus infection and replication is actively being pursued. The consequence of such research has been increased activity in the design of chemical analogues which would perturb the structure and thus inactivate the virus. Preliminary reports have suggested that at least one compound has been made which demonstrates the predicted properties. This compound, which is active against both influenza A and B is currently being tested in animal models.

PERTUSSIS

Question. Dr. Fauci, we continue to hear of the problems with side effects of the currently available pertussis (whooping cough) vaccine. I know you have a major effort in this area. Could you please update us on the status of your program to develop an improved pertussis vaccine?

Answer. Several American and foreign manufacturers are successfully developing new acellular pertussis vaccine candidates which may eventually be marketed within the U.S. These manufacturers include: Lederle, Connaught (Canada), Merieux (France), Biken (Japan), Michigan Department of Public Health, Massachusetts State Health Laboratories, CAMR/Porton International (Great Britain), Sclavo (Italy), Smith Kline Biologicals (Belgium) and the National Institute of Child Health and Human Development, NIH/AMVAX. The vaccines basically contain either inactivated pertussis toxin alone or inactivated pertussis toxin combined with filamentous hemagglutinin protein. Several of the vaccines also contain known amounts of a third and/or a fourth antigen referred to as agglutinogen or fimbriae, and a 69kD outer membrane protein. "Investigative New Drug" applications to test a trivalent formulation consisting of diphtheria, tetanus and pertussis antigens, have already been submitted to the FDA for the majority of these products.

Clinical trials of acellular pertussis vaccines remains a top vaccine development priority for NIAID and for the PHS. NIAID has been delegated the authority to conduct efficacy trials for the National Vaccine Program (NVP), the administrative locus of pertussis vaccine initiatives for the Department of Health and Human Services. The NVP will provide NIAID $2.948 million, which was appropriated to the NVP in FY 1990 to support the trial. Similar amounts will be available for FY 1991-1993.

In preparation for the trial, several complementary activities are underway including a multicentered coordinated phase II clinical trial in all six of NIAIDs contracted vaccine evaluation treatment units to evaluate promising candidate vaccines for safety and immunogenicity in infants. The data will be used as a basis for recommending one or more vaccines to be used in the efficacy trial which is scheduled to begin sometime in the second quarter of 1991. Visits have been made to potential field trial sites identified through an earlier solicitation, and information about the suitability of other potential sites is available. Data from continuing analysis of the Swedish trial is assisting in the selection of study design features for the upcoming efficacy trial.

The efficacy study in Sweden has been completed. The results indicate that the two Japanese vaccines used in the study were safe and efficacious, especially for serious disease, but without any good correlation between protection against disease and a host response to vaccination. Because the trial in Sweden did not confirm any serological correlates of protection, considerable effort will be devoted to a search for such correlates in the new Phase III trial. Several other large scale field trials are now being planned independently in Great Britain, Germany, Senegal, and Sweden, but will require at least three to five years before they are completed. Research on the development of a recombinant DNA pertussis vaccine has progressed significantly during the past year at several different laboratories. Recombinant proteins have been isolated and purified and shown to be immunologically and enzymatically active. Other work has involved the modification of the pertussis genome, mutagenesis for the development of a safe and inactivated toxin product. We anticipate that one of the candidate pertussis vaccines to be tested this summer in NIAID's vaccine evaluation units will consist of a recombinant DNA product.

TRAINING

Question: Dr. Fauci, last year we provided you additional resources for training. Do you feel that further training resources are needed?

Answer: Although we have made significant progress in the past 5 years in a vast number of critical scientific areas, and are at the threshold of a number of scientific breakthroughs, there is an urgent and pressing need for an increased cadre of trained scientists in every discipline. Additional microbiologists, immunologists, molecular biologists and virologists are needed to combat AIDS, sexually transmitted diseases, asthma, fungal and parasitic diseases, hepatitis and in vaccine development.

Our budget for training in FY 1990 is $17,493,000. With these dollars, we will be able to fund 670 full time training positions (FTTPs). However, due to increasing tuition rates, cost of supplies and overhead, the commitment of resources on training does not translate directly to an increased number of trained scientists. At present, the average cost of one trainee including tuition, books, stipend, supplies and incidentals is about $28,000 per year. In my professional opinion, we need to double the number of training slots. This is necessary to enable us to avert a critical shortage of basic scientists and physician scientists as we enter the next decade.

COMMUNITY PROGRAMS FOR CLINICAL RESEARCH ON AIDS

Question. Last year NIAID embarked on an innovative program called "Community Programs for Clinical Research on AIDS (CPCRA)" which was designed to bring community based treatment centers, poor and minorities, into the "NIH AIDS research net."

New York Medical College, whose affiliated institutions have an AIDS population of three thousand, mostly black and Hispanic patients, applied to participate in the CPCRA program.

In June 1989, NYMC was informed that its application was "out of the competitive range" for the program. They were told further that the reasons why they were turned down could not be disclosed until the contract awards were made.

Those awards were announced on October 5, 1989. The Office of Grants Administration of New York Medical College has repeatedly requested the reasons why their application was denied.

The reasons should be readily available. I assume that the peer review committee wrote them down when it met to decide on the award of the CPCRA contracts.

Would you please furnish the committee:

a) the names of all members of the peer review committee for the CPCRA contract

b) the minutes of the deliberations or a summary of those deliberations

c) the criteria that were used for the contract awards

d) the reasons for the peer review committee's decisions.

Answer. The following are the names of the members of the peer review committee for the CPCRA contract:

Fischl, Margaret A., M.D. (Chairperson)
Associate Professor
Department of Medicine
University of Miami School of Medicine
Miami, FL

Bloch, Earl F., Ph.D.
Associate Professor
Department of Microbiology
College of Medicine
Howard University
Washington, D. C.

Boyer, Cherrie B., Ph.D.
Assistant Adjunct Professor of Pediatrics
Division of Adolescent Medicine
University of California Medical Center
San Francisco, CA

Britton, Carolyn B., M.D.
Assistant Professor of Neurology
Director, Neurology Ambulatory Care
Neurology Institute
College of Physicians and Surgeons
Columbia University
New York, NY

Evans, Caswell, Jr., D.D.S., M.P.H.
Director, Public Health Programs
County of Los Angeles Department of Health Services
Los Angeles, CA

Habtemariam, Tsegaye, D.V.M., Ph.D.
Professor and Director
Biomedical Information Management Systems
Department of Epidemiology
Tuskegee University
Tuskegee, AL

Jaffe, Harold W., M.D.
Chief, Epidemiology Branch
AIDS Program
Centers for Disease Control
Atlanta, GA

Martinez, Cervando, Jr., M.D.
Professor of Psychiatry
University of Texas Health Science Center
San Antonio, TX

Mitchell, Janet L., M.D., M.P.H.
Chief of Perinatology and Assistant Clinical Professor
Department of Obstetrics and Gynecology
Harlem Hospital Center
New York, NY

Novick, Alvin, M.D.
Professor
Department of Biology
Yale University
New Haven, CT

Pujols-McKee, Ana, M.D.
Medical Director
Family Medical Care Services
Department of Public Health
City of Philadelphia
Philadelphia, PA

Rhame, Frank S., M.D.
Assistant Director
Department of Medicine
University of Minnesota Hospital
Minneapolis, MN

Saz, Arthur, Ph,D.
Professor Emeritus
Department of Microbiology
School of Medicine
Georgetown University
Washington, D.C.

Torres-Anjel, M.J., D.V.M., Ph.D.,
Executive Secretary
Epidemiology and Technology Transfer
  Subcommittee, AIDSRRC
Program and Project Review Branch
Extramural Activities Program
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD

Hornbeck, Hortencia, Ph.D.
Executive Secretary, AIDSRRC
Chief, AIDS Review Section
Program and Project Review Branch
Extramural Activities Program
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD

The following document outlines the criteria that were used for the contract awards:

STAGE II	WEIGHT
A. Technical Approach	50
(1) Demonstration of a thorough awareness and overall understanding of the specific tasks to be performed and the methods and resources to successfully accomplish these tasks. Understanding of potential problems that could reasonably be encountered and how they would be resolved.	(15)
(2) Demonstration of organizational experience in the planning, design and conduct of community based clinical trials.	(15)

(Organizational experience includes the conduct of past research protocols, results of such research, quality assurance documentation or other pertinent documents.)

(3) Adequacy of proposed plan and timetable for accomplishing tasks. (5)

(4) Integration into the community of which it is a part. (15)

*Refer to the Work Statement Instructions to Offerors of Stage II Proposals beginning on page 20 of the amended Work Statement.

B. Personnel Expertise 20

Demonstrated qualifications, availability, competence, experience, and adequate mix of professional and technical personnel to implement and conduct this project as demonstrated in part by:

(1) Experience of the Principal Investigator and other key medical personnel in the care of HIV-infected individuals and in the conduct of clinical trials. (10)

(2) The experience, managerial competence, and the time commitment of the Principal Investigator to the proposed program. (5)

(3) The experience, competence, training, and technical competence of other staff to accomplish project tasks. (5)

C. Patient Population 10

Adequacy and availability of the patient population and recruitment and follow-up plan for the conduct of community-based studies.

D. Organizational Structure 10

Adequacy of an organizational structure that will allow accomplishment of the work in an efficient manner.

Adequacy of specific plans for management and coordination of tasks, quality control, compliance to task schedules. Adequacy of a management plan that includes an organizational chart that details clearly defined lines of authority and responsibility and a staffing plan that provides full support to meeting the requirements of all tasks.

*Refer to the Work Statement Instructions to Offerors of Stage II Proposals beginning on page 20 of the amended Work Statement.

E. Facilities 10

Demonstration of existing medical, accounting and technical facilities specific for the conduct of community-based clinical research.

TOTAL 100

In regards to your inquiry on the reasons for the peer review committee's decisions, I would like to emphasize that the competition for these awards was very great. The solicitation for proposals resulted in over 700 requests for the Request for Proposal package, the largest response ever to any NIAID solicitation, and 68 proposals were received. Many offerors submitted proposals that we were unable to support due to the limitation of funds in this first cycle of this pilot project. The proposal submitted by the New York Medical College was reviewed by this Committee and found not responsive to the evaluation criteria published in the Request for Proposals. The peer review process culminated in the award of contracts to 18 community based organizations located in 14 cities where the AIDS epidemic is severe.

This process resulted in the funding of contracts to organizations of the highest scientific and medical calibre, representing a high level of geographic, racial, and risk group diversity. These programs are furnishing an extraordinary level of access to "hard to reach" groups and a clear commitment of these principal investigators to the service of those patient populations currently underrepresented in HIV research.

The clinicians in these 18 programs currently care for over 30,000 HIV-infected persons. All funded organizations have the following characteristics: they are composed of groups of licensed physicians and nurses who serve as primary care providers for HIV-infected patients; they have access to a large number of infected people, with particular emphasis given to underrepresented populations, such as minorities, and intravenous drug users; they have substantial experience treating HIV-infected people; they have demonstrated support from the community served by the organization; and they have established relationships with community health care facilities, such as hospitals and regional tertiary care centers, to ensure that the organization has a track record of commitment and service to the community and it is integrated within the local medical care structure.

Question. Finally, when do you contemplate responding to the repeated requests from the Office of Grants Administration at NYMC?

Answer. A letter detailing the basis for the decisions made by the peer review committee was sent to the Office of Grants Administration at New York Medical College on February 8, 1990.

Question. What is the average cost of each patient enrolled in the Community Programs for Clinical Research on AIDS?

Answer. CPCRA research will take place in communities affected by the HIV epidemic by community clinicians and institutions. There will be a tremendous diversity in the conduct of this research, because it will be done within the context of primary care in a variety of community settings. Each awardee of a CPCRA contract has received a dollar award, within which he must conduct this research. Because of the diversity within the program, however, it is not possible to estimate the per patient cost at this time. After the study is underway, however, the NIAID will collect this type of data and will be happy to provide it to you when it becomes available.

Question. What is the average cost for the data obtained for each patient in the program?

Answer. Because the CPCRA is just beginning to get underway, we cannot presently estimate the average cost for the data obtained for each patient in the program. The NIAID will be able to furnish you that information when it becomes available.

Question. What are the projections for the cost of data per patient in the program through 1992?

Answer. As stated before, because the CPCRA is just beginning to get underway, we cannot estimate the cost of the data per patient in the program through 1992. After the study is underway, however, the NIAID will collect this type of data and will be happy to provide it to you when it becomes available.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

Question. Dr. Fauci, what action will the NIAID take in fiscal year 1990 to expand outreach and participation for underserved populations, particularly within minority communities with high incidence of HIV populations? What steps have been taken to coordinate outreach with existing federally supported programs providing counseling and care to those infected with AIDS?

Answer. NIAID is taking several steps in fiscal year 1990 to expand outreach and participation for underserved populations, particularly in areas in which HIV infection is spreading rapidly. We are using several means to increase the participation of minority populations in the clinical trials. A new Request for Application (RFA) under development, entitled the Expansion of the AIDS Clinical Trial Group to Underrepresented Minorities, is expected to appear in the NIH guide early this year with the first awards anticipated for the Fall of 1990. Recognizing the importance of collecting data that includes minorities, we are working to increase minority participation in our studies through this RFA by several means, for example, by including provisions for bringing the necessary social services to potential minority participants. Although we are making progress in recruiting minorities into the system, we have strengthened our resolve to increase minority representation even further in our studies.

To address the special needs of minority children with HIV infection, who comprise 89 percent of pediatric AIDS patients, we increased the number of pediatric AIDS clinical trials units receiving funding to 15 in 1988, enabling researchers to begin phase II and III trials in children. A new initiative will be published in the near future that will further expand our efforts to reach HIV-infected children and pregnant women. Awards for this initiative are expected to be made in the Fall of 1990. We have also strongly encouraged the existing units that accrue primarily adults to begin pediatric studies as well. As a result, several have begun these vital studies. Another important component to the expansion of the pediatric trials units is the establishment of perinatal centers serving women in at-risk populations. This feature will provide for increased attention given to pregnant HIV-infected women and their children in AIDS clinical trials.

A newly begun initiative that brings treatment research to community-based clinics and physicians is the Community Programs for Clinical Research on AIDS (CPCRA). The CPCRA broadens research opportunities to women, minorities, and intravenous drug users and the clinicians who care for them. This initiative will provide wider access to experimental therapies for HIV infection and its sequelae. Enabling the participation of community-based clinicians and organizations in clinical research also extends participation in well-designed clinical studies to persons currently underrepresented in NIAID-supported HIV research, specifically, minorities, sexual partners of HIV-infected persons, and intravenous drug users.

The CPCRA awardees represent exceptional geographic, racial, and risk group diversity. These physicians are providing to "hard to reach" groups an extraordinary degree of access to clinical trials for potential new therapies for HIV infection and associated diseases. The individual programs have shown a clear commitment to the service of those patient populations currently underrepresented in HIV research. Patients enrolled in clinical trials under the community program will work closely with their primary care physicians, an arrangement that should greatly facilitate their access to information about their disease as well as available treatment options and research opportunities.

Finally, NIAID is currently working with the National Institute on Drug Abuse on a project aimed to increase participation of intravenous drug users in NIAID-sponsored clinical trials.

Question. Dr. Fauci, I am advised that we are seeing an increase in the number of Americans affiliated with asthma, particularly among inner city youth. Would you describe for the Subcommittee any efforts the Institute has underway, or plans to undertake concerning this problem?

Answer. The past decade has witnessed not only an increase in the prevalence of asthma in the inner city, but some data suggest that the mortality rate may be increasing among inner city African Americans and Hispanics as well. These changes have been attributed to a variety of factors ranging from adverse environmental exposures, such as increased pollution, to inaccessibility to health care due to socio-economic inequities.

For this reason we have launched a National Cooperative Inner City Asthma Study which is designed to identify and elucidate precisely what factors are responsible for the increasing morbidity and mortality in these populations followed by a structured therapeutic intervention aimed at reducing or eliminating these factors in the study population. It is also anticipated that this will provide information upon which future interventions can be designed.

REDUCTIONS IN CANCER DEATH RATES

Senator HARKIN. Let us start at the beginning. Let us go back to start with the Cancer Institute. Dr. Broder, let me start off with a question that I have had some people ask me, and I thought, well, I would ask you. It has to do with the amount of money that we have spent on cancer research.

Since 1971 when President Nixon declared war on cancer, we have spent approximately $16 billion on cancer research. In the 1990's I expect we will spend at least that amount, perhaps more. Despite this level of spending, the overall deaths from cancer increase each year, while the rates from other major causes of death decline. In 1950, cancer caused 15 percent of all U.S. deaths. In 1985, 24 percent.

Although some of the increase is due to an aging population and people living longer, even the age-adjusted cancer mortality rate continues to climb. The incidence in death rates for those under and over 65 are on the rise. What are the cancer death rates for those both under and over 65? Are we making progress, or are we falling behind?

Dr. BRODER. Sir, thank you for the question. I think this is a complicated question and one that does merit a very specific response.

We have made progress against cancer, particularly for white Americans under age 65. I am going to use the death rate as the final parameter against which everything has to be measured, and using the death rate, the number of cases per 100,000, age-adjusting the population, at the time of the founding of the National Cancer Act in its current form, for people under age 65 we have seen a 15-percent reduction in colo-rectal cancer—in the death rate—a 25-percent reduction in ovarian cancer, a 28-percent reduction in stomach cancer, a 32-percent reduction in bladder cancer, a 37-percent reduction in uterine cancer, a 39-percent reduction in cervical cancer, a 20-percent reduction in cancer of the oral cavity and related areas, a 26-percent reduction in thyroid cancer, a 52-percent reduction in Hodgkin's disease-related deaths, and a 61-percent reduction in testicular cancer deaths. These are all death-rate reductions.

Senator HARKIN. This is death rate per 100,000 under 65?

Dr. BRODER. Yes; this is the actual reduction in death rate, absolute bottom line, nonnegotiable, no funny numbers. That is, taking the rate of death as it would have existed in 1973 and then using that and watching, for people under age 65, a decline in that death rate.

The last set of figures we have, because we are a couple of years behind, is 1987, so I am giving you the latest available figures. We are always approximately 2½ years behind, because of our statistical end result compiling factor, but I believe these are very accurate figures.

Senator HARKIN. Now, this is death rate per 100,000?

Dr. BRODER. That is correct. In each case, I have given you the percentage reduction of death rates.

INCREASES IN CANCER DEATH RATES

Senator HARKIN. Under 65, only white population?

Dr. BRODER. I am giving you the data base for all individuals under age 65, but I will break out in my discussion several areas where we have not made adequate progress.

I am showing you a decrease in death rate for those cancers I have picked for the most part common tumors, because one criticism is that we are only focusing on uncommon tumors. I want to stress that under age 65, by any reasonable measure, for many common tumors we have had an absolute reduction in death rate for the tumors that I have listed.

However, over age 65 we have not made adequate progress, and for some specific categories of the population—for example, for minority groups, for individuals who are poor, and for certain other categories—native Americans, native Hawaiians, and so on, our cancer statistics are not good.

I also want to stress that in some areas we have lost ground. The death rate for women who die of lung cancer has gone up nearly 100 percent since 1973.

Senator HARKIN. Now, more women die of lung cancer than breast cancer?

Dr. BRODER. I am sorry to tell you that that is correct. We expect in this particular year, fiscal year 1990, we expect approximately 50,000 women will die of lung cancer and approximately 44,000 women will die of breast cancer.

What I would like to say is that under age 65 we have made progress, and the technologies of the Cancer Institute have, in no small measure, contributed to that reduction of death rate. But on the other hand, for people over 65 and in certain categories we need to do a better job.

For example, in black Americans, picking one very important tumor, colo-rectal cancer—cancer of the large bowel—black Americans in this country in the early 1970's actually had a lower death rate than white Americans.

Since that time, since the founding of the National Cancer Act—perhaps some would say that the National Cancer Act contributed to this—the death rate for white Americans has continued to fall for cancer of the large bowel in each successive year. On the other hand, in 1975, the death rate for black Americans crossed, and is now increasing, and is higher than the death rate for white Americans. So we have had an intersection of the two lines and there is a widening gap between those death rates.

ANALYSIS OF DEATH RATES

Senator HARKIN. Can any of that be attributed to better screening or better diagnosis of exactly what is causing the deaths?

Dr. **Broder**. I think that all of these issues can be important—the totality of it can in fact be understood as three factors: prevention, early diagnosis, and treatment. We think that all three have to be relevant factors. Access to medical care and access to the technologies of the National Cancer Institute are critical and important, and for individuals who do not have access to them, or perhaps do not have them available, we can see differentials in the death rate. This is my assessment of these statistics.

That is why I stress there is good news and bad news in the death rate. We are not making as much progress as anyone would like to see for individuals over the age of 65 and in other categories. I would also like to stress that lung cancer is an enormous, over-driving factor in all death rate figures and has an enormous effect on the overall cancer mortality figures, for people of all ages.

Senator **Harkin**. In 1950 cancer caused 15 percent of all United States deaths and in 1985 it was 24 percent.

Dr. **Broder**. That is correct.

Senator **Harkin**. Even though some cancer death rates are going down, what has driven that up to 24 percent?

Dr. **Broder**. If you are looking at a probability of someone dying of cancer, one issue you have to be careful about, particularly going back to 1950, is that there were other factors in society that were the causes of death, and therefore the proportion can change.

The percentage can change, as there may be improvements in infectious diseases or other diseases. People do not die from tuberculosis, for example, in this country, at the same rate as they died in 1950, and cardiovascular deaths have decreased, and so on.

That is why, to me, the bottom line is the death rate. That is why I stick with that figure, and I like to use that as the statistic. It is an endpoint that I feel everyone can understand, and by that parameter, the death rate for people under 65 has fallen.

As our prevention, early diagnosis and treatment modalities become more widely implemented, we expect that if we prevent a disease in someone who is under age 65, this will benefit all cancer statistics. For example, if we can prevent lung cancer or colon cancer by appropriate prevention, changes of lifestyle and whatever, as those people reach the age of 65 and go beyond it, they will decrease the death rate for people over 65 as time passes.

Senator **Bumpers**. Mr. Chairman, would you yield?

Senator **Harkin**. I was going to yield to you anyway.

COLON CANCER IN BLACKS

Senator **Bumpers**. I wanted to ask Dr. Broder, is the incidence of colon cancer, which seems to be escalating among blacks, for example, related to diet?

Dr. **Broder**. We think it is multifactorial. We think it may in fact be in part related to certain dietary issues. It may also be related to a lack of access to early diagnosis and treatment. Early diagnosis and treatment can make a big impact for certain forms of large bowel cancer. We have seen that. For example, in cancer of the rectum, the death rate associated with that cancer has dropped 40 percent.

Since 1973—a great deal of that has to do with implementations of early diagnosis and followup therapy. We have better radiation therapy, better surgery and so on, and so for some diseases it makes a big difference as to whether you have access and are in the system and are being able to derive benefits of the technology that is being developed.

But I do not want to leave you with the impression that any of us in the National Cancer Program are satisfied with the cancer statistics.

SMOKING AND LUNG CANCER IN WOMEN

Senator **Bumpers**. The incidence of lung cancer among women, which seems to be skyrocketing, or at least has now overtaken breast cancer as a cause of death among women, is related to increased smoking rates among women, correct? When I was younger it was fairly uncommon to see women smoke.

It was not considered acceptable, and then as it became more acceptable women began to smoke as much as men. Is this increase now a result of that 30- to 40-year period when smoking rates for women increased? Are we just now reaping the whirlwind on that?

Dr. **Broder**. Yes, sir; we are reaping the whirlwind. Smoking is one of the few things that I am aware of which is lawful, and which is lethal when used as intended. I think that basically we really have a situation where women, perhaps in the late 1950's, began to smoke and we are now paying a significant price for that.

I am also exceedingly disturbed by reports—I do not have firsthand knowledge to know whether they are true, but I am exceedingly disturbed by reports in the newspaper, in the lay press, which suggest that women, particularly young women, are being targeted for initiation into smoking practices. I hope my words are not misunderstood, but if that practice really does catch on, then some future director of the National Cancer Institute will have the sad duty to tell you that lung cancer death rates are probably not going to fall in that group.

EDUCATION ON SMOKING

Senator **Bumpers**. I saw a report the other day that tobacco companies are targeting high school graduates who are not likely to get any additional training past that.

There is just something about that that really is offensive to me. I cannot articulate it very well, but I just cannot believe that the bottom line would dictate that the people who are the most vulnerable, would be targeted by the tobacco companies because of their lack of education and understanding about the consequences of their conduct.

Dr. **Broder**. Sir, that is part of it. I believe someone who is 18 to 22 years of age has a belief in his or her immortality. It is very difficult for a person who is at that age to recognize that there will be health consequences at some later time of life which they cannot avoid once they have made a commitment to certain behavior.

Senator **Harkin**. I was going to followup on that by saying we are trying to do more in terms of early childhood education on drugs: awareness of drugs and how to say "no" to peer pressure to take drugs. However, almost every case I have seen focuses on hard drugs, marijuana, alcohol, almost nothing dealing with tobacco.

It seems to me we are doing a woefully inadequate job in this country of early childhood education in kindergarten, first, second, third, up to—K through eight, of educating these kids that tobacco is a drug, a lethal drug. It is an addictive drug, and it is going to kill you.

But nothing is happening out there. They are focusing on cocaine and they are focusing on everything else, but they are not focusing on tobacco. Through the action of the school boards and principals some schools in my home State are making schools smoke-free zones where even teachers cannot smoke.

They cannot smoke in the school, in the lunch rooms, in the teacher's lounges, at basketball games, or at football games, even though that is outside. This should be true for every elementary and secondary school, sports area or any kind of facility in the United States. Smoking should not be allowed and we need ongoing educational programs.

Senator BUMPERS. Mr. Chairman, when I came to the Senate 15 years ago, a room like this would have been filled with smoke. Now it would be unthinkable for anybody to light a cigarette in this room.

CANCER CENTERS CRITERION AND SMOKING

Dr. BRODER. We have changed one of our criteria for the comprehensive cancer centers, which is a very important foundation stone of the National Cancer Institute, to build in for centers which are designated as comprehensive, the requirement to do community service and outreach activities in order to be given that name.

We have an expectation that among the community service and outreach activities that comprehensive cancer centers will do, will be to play an important role in their communities, much as you are describing, to have an impact on smoking and smoking-related cancer deaths in their communities.

Senator HARKIN. I am told that in Canada they have a tax on cigarettes. It is about $4 a pack for cigarettes in Canada.

Now to my way of thinking, if we have that many people dying of lung cancer and they need treatment, maybe they ought to pay for it.

DEVELOPMENT OF AZT

Senator BUMPERS. Dr. Broder, was AZT developed by the National Cancer Institute?

Dr. BRODER. I believe it is fair to say that AZT is a product of both the viral cancer program and the developmental therapeutics program of the National Cancer Institute, starting with a commitment that occurred approximately 25 years ago.

The first synthesis of AZT was done under an NCI grant by Jerome Horowitz in 1964, at what was then the Detroit Institute for Cancer Research and is now the Michigan Cancer Foundation.

Senator BUMPERS. Do we license Burroughs-Wellcome to make that medicine?

Dr. **Broder**. No; the drug is manufactured by the Wellcome Research Laboratories without a license from the Government.

Senator **Bumpers**. Could we legally license someone else? If we developed it with one of our research grants, why do we not have more control over who makes it?

Dr. **Broder**. The history of AZT is complex. I think it is fair to say that it is a collaboration between Government scientists and private sector scientists. Are you asking whether the Government could lawfully manufacture AZT and distribute it? Is that the question?

LICENSING AND REASONABLE PRICING OF DRUGS

Senator **Bumpers**. Well, either that or license somebody else. What I would like to see is the price of AZT dropped, and some old-fashioned competition might do that.

Dr. **Broder**. We feel, and perhaps Dr. Fauci would speak more to this point, that the National Institutes of Health is a prime catalyst for competition in drug development. Many other drugs are being developed, and we feel that if they are successfully shown to work by controlled trial methodology that there will be competition.

In addition, the NIH and particularly the NCI now, for all drugs for which it has right and title—which would be any drug that a Government employee invents—puts a reasonable price clause into the licensing of such a drug for the commercial sector, and my understanding is that such a reasonable price clause would be enforceable.

LICENSE FOR DDI

Senator **Bumpers**. I will ask Dr. Fauci about this in a moment, but is NCI right now not doing clinical trials on a drug called—is it ddI?

Dr. **Broder**. Yes, sir; such a reasonable price clause is attached to ddI. That drug was licensed to the Bristol Myers Co. and they have a clear understanding of what the agreement is. Whenever we put in a reasonable price clause the commercial company is on notice that the Government is serious about that.

COST OF AZT TREATMENT

Senator **Bumpers**. Dr. Fauci, I will direct this question to you. What is the approximate cost of AZT treatment for an early diagnosis of an AIDS patient? I think you have recommended lower dosages than you recommended in the past. Is that not correct?

Dr. **Fauci**. Right; most recently, a study sponsored by the NIAID has demonstrated that AZT is as effective with less toxic side effects at one-half the original recommended dose from a couple of years ago, so that will have an important impact on the cost of AZT.

The recent studies now indicating that AZT is effective in delaying the onset or progression of symptoms in individuals early on in the course of infection, some of whom have no symptoms at all, has enormous implications for hundreds of thousands of Americans.

So when you combine a decrease in the AZT dosage with the decrease in price that the company's charging for AZT, the result is a reduction in the cost of AZT per patient.

But the point that Dr. Broder made is that we have other drugs in clinical trials right now, some of which are associated with the Technology Transfer Act agreement of a reasonable price clause. I think a combination of all of those things, particularly, as you yourself mentioned, some good old-fashioned competition, is going to bring the price down over the next year or so.

Senator **Bumpers**. What is the approximate annual cost?

Dr. **Fauci**. That is approximately $6,000 to $8,000 per year per person. It originally started off at $12,000, and then dropped to approximately $8,000 and now it's dropping even more.

PROPOSED ELIMINATION OF FUNDS

Senator **Bumpers**. How do you feel about Dr. Mason's proposal to eliminate roughly $29 million that we appropriated this year to help AIDS patients with their AZT, their financial problems of getting AZT?

I do not want to put you at odds with your boss. I just take strong exception to the idea that we should eliminate that money. Take a young man who tests positive and he is making $25,000 a year.

Let us assume that he is making $25,000 a year. He is making a house payment or he is trying to pay for a car and an apartment. He is not going to be able to pay $8,000 a year for AZT treatment.

And we have been putting money into this budget to help some of those kids and they say no, this is unfair because it discriminates in favor of AIDS patients.

I think their argument is fallacious because here we are saying, you are not going help somebody go to the drugstore and buy AZT because that would give him an advantage.

I would like to have your comments on it. I am not asking you to take issue with me or Dr. Mason, but I just——

Dr. **Fauci**. It is somewhat difficult to give a comment without taking issue with either you or Dr. Mason, but I can tell you as a physician, and I will speak as a physician, that I find it a very serious problem, particularly with AIDS, which is the area of my primary interest. Individuals who are infected with HIV or who are ill with HIV infection do not have the wherewithal to pay for the cost of the drug.

I do not know what the solution to the problem is, but I feel that, as a physician, that under no circumstances should a person be denied treatment or care because of the fact that they cannot afford it. I have felt that way ever since I have been a physician and even before.

PROGRESS OF AIDS TESTING

Senator **Bumpers**. Well, Dr. Fauci, I could not agree with you more. I think education, health care, and housing ought to be guaranteed by any society that considers themselves a really compassionate and great society. I am going to insist with the chairman of this committee that we put that money back in.

I think it is outrageous to say to AIDS patients, yes, you need AZT early on, but if you do not happen to have the money to do it, it is tough luck.

Let me ask you one other question. Are we making any progress in AIDS testing? The last figures I saw showed that AIDS often will not show up on the tests that we now have, sometimes in cases as long as 5 to 7 years. Is this true?

Dr. FAUCI. If you are talking about detection of infection, yes; the antibody test may not show up as positive for a considerable period of time.

Senator BUMPERS. I am talking about the AIDS antibody test.

Dr. FAUCI. There has been a lot of discussion and publicity about that, particularly related to a few papers that have appeared in the medical literature over the past year.

Certainly, it is a relatively uncommon event that an individual will go for years being infected without the standard classic elisa or western blot test being positive.

The technology that has been developed over the past year to detect early infection, perhaps even before one has any possibility of detecting an antibody, is a test called a polymerase chain reaction which has the capability of amplifying the genes of the virus and making it detectable at the earliest possible time, even with a very low burden of virus in the body.

In addition, culture techniques themselves have been able to detect what we call plasmaviremia in virtually everyone who is infected with HIV.

The culture techniques and the molecular biological approach over the past year I think have made our degree of accuracy in detecting HIV in people much better. It still is not 100 percent, and Senator, it will never be 100 percent.

Senator BUMPERS. Oh, it will never be?

Dr. FAUCI. I would be very surprised if we would have a situation where you would be able to detect in 100 percent of the cases everyone that is infected. That is just the biological variability that you see in virtually any infection.

What we try to do is bring it down to its very bare minimum of undetectability. I think we made some important advances over this year in the two areas that I just mentioned.

Senator BUMPERS. So at what stage of the infection, from the time of exposure to HIV, how long after that could you achieve, say, a 70-percent or 80-percent accuracy rate?

Dr. FAUCI. Based on numbers from the Centers for Disease Control, within 5½ months, you would have an antibody test in 95 percent of the individuals who are infected using a standard antibody test.

So you are talking now about the vast majority of people within 5 months. Today, however, when an individual is infected within approximately 3 to 6 weeks and perhaps 3 months, you would get the majority of people turning antibody positive, but 95 percent of them within 5½ months.

Senator BUMPERS. Well, that is very encouraging, Dr. Fauci.

Dr. FAUCI. Yes; well, what happens, Senator Bumpers, is that studies get published in which a certain number of individuals are reported in the literature as having been infected and not having the antibody test turn positive when you look retrospectively anywhere from a year for some people to as long as 3 or 4 years for other people.

They focus on that small number of people and do not necessarily have an accurate denominator from which those people come. So the impression of the general public is that it is a very common event for someone to be infected and have an undetectable antibody, when, in fact, that is an unusual occurrence. It does occur, and we cannot deny that, but it is unusual.

CANCER INFORMATION DISSEMINATION

Senator **BUMPERS**. Well, that is very educational and very helpful.

Dr. Broder, back to you. I assume that you saw this article, I guess it was in that Monday health edition of the Washington Post, where this debate over how quickly the findings of cancer researchers ought to be disseminated among doctors in this country.

Did you read that article?

Dr. **BRODER**. Sir, I not only read it, I have lived it. [Laughter.]

CONTROVERSY OVER CLINICAL ALERTS

Senator **BUMPERS**. Well, I was pleased to hear you awhile ago because long ago I saw a story about a new treatment for colon cancer where apparently maybe even the liver is involved but you have a new medicine which you say has reduced the death rate by one-third.

That was one of the findings, and apparently the National Cancer Institute sent out a medical alert or a cancer alert. Because there was so much controversy about that, I think you downgraded that to something called a medical advisory?

Dr. **BRODER**. Sir, we called it an update, but it walks like an alert and talks like an alert and quacks like an alert.

Senator **BUMPERS**. Why don't you just comment on this because I happen to be on the side of the people who think this information ought to be disseminated at the very earliest possible time.

Dr. **BRODER**. We have a very strong commitment within the National Cancer Institute to disseminate information quickly following the appropriate process of peer review.

INFORMATION DISSEMINATION

Senator **BUMPERS**. Who are your detractors on that, Dr. Broder? Who are the people who think that you put that information out too quickly?

Go ahead, call——

Dr. **BRODER**. I think that there is, in any large program, always a diversity of ideas, and I think that there are some individuals who believe that cancer research results, particularly as they affect treatment, should be first published in the literature and then have a process of dialog and discussion. They want an evolutionary process which allows information to be disseminated.

We feel that we need to do a more quicker and better job of getting information out to the practicing physicians. We need to use electronic databases, and we are encouraging doctors to use computer technology which gives them up-to-the-minute information about new protocols.

We have given a very strong emphasis to our cancer information services. The committee last year recommended that we increase that, and we have significantly increased the cancer information services which allows the public direct access to information.

But in particular, we feel that we cannot always wait for a natural evolutionary process to get information out, and therefore, at the conclusion of studies where something is definitive, we feel that it is important to have a process in which we can get information directly into the hands of practicing doctors.

And I am pleased to tell you that, although there are detractors and that there will always be a divergence of opinion, I think we are achieving a significant consensus.

We had a workshop directly addressing this point in January of this year. There was a very high level of enthusiasm and consensus on the idea that we need to do more and do a better job of getting information out.

In particular, we are in agreement on the principle of not allowing what amounts to bureaucratic delay affect the information knowledge dissemination. But we do, at the same time, have to adhere to controlled clinical trials and make sure that we have a good scientific basis and not take shortcuts at that level.

Once there is an important piece of information, we need to disseminate it and act accordingly. That is the philosophy of the Cancer Institute.

COORDINATION WITH CDC

Senator **Bumpers**. Mr. Chairman, just one final question of Dr. Broder. Is NCI coordinating its breast screening awareness programs with the CDC?

Dr. **Broder**. We have very good working relationships with the CDC and with other agencies of the Public Health Service. We exchange statistics and exchange information. We particularly exchange information based on what is called our SEER data base, statistical epidemiology and end results. We do have an excellent and effective working relationship on the topic of mammography, but not confined to that, with the Centers for Disease Control.

Senator **Bumpers**. Mr. Chairman, I probably have one or two written questions for Dr. Lenfant and another one for Dr. Fauci.

CANCER IN RURAL AREAS

Senator **Harkin**. Thank you, Senator Bumpers.

Dr. Broder, just a couple of additional ones. Last year we requested you to develop more focused statistics with regard to the incidence of cancer in rural areas.

It is my conviction, based upon observation, not much more than that and having lived a lifetime in rural areas that, due to the exposure of chemicals and other things, there is a higher incidence rate of cancer in rural areas.

Is that so, or do you even have the statistical basis on which to make that judgment and what are you doing to develop a more comprehensive statistical series on the incidence of cancer in rural areas?

Dr. **Broder**. We are very concerned about a number of issues that relate to rural health as it applies to cancer. We have established a meeting and we will have a task force that will deal specifically with the special problems of rural cancer as it relates to prevention, early diagnosis and treatment.

We will expand our statistical epidemiology and end results program, which is how we monitor the cancer statistics and allowed me to give you some of those statistics earlier in my presentation. I think it is important to know that we have made a special effort to have statistical data bases in rural areas throughout the history of those programs.

It perhaps is of some interest to specify that Iowa, New Mexico, Connecticut, Utah, and certain parts of Georgia are definitely covered in our statistical end results base, and as we speak we are gathering information on those areas.

In addition, we have made a special effort to develop cancer information services, the kinds of direct interaction with the public, and to make sure that we get direct cancer knowledge into the hands of the public.

We have made special efforts to have rural areas covered in our cancer information system, and we have expanded the cancer information system in this fiscal year.

We are covering Kentucky, West Virginia, Virginia, South Carolina, Utah, and New Mexico with special programs, and these are States that have a significant rural component.

In addition, in the State of Virginia, we have a very innovative program by a cancer center, in collaboration with our cancer information service, to reach new ways of dealing with impoverished rural populations in a particular way. We are exploring what to do when reading skills are not up to complete standard levels. We are trying to work out new ways of communicating about cancer in a population that may be disadvantaged with respect to certain information skills—learning how to improve those skills and to making certain that we are getting effective cancer knowledge.

There are some people in this country who cannot even dial our 1-800-4-CANCER number because of several factors, and we want to be able to reach such individuals. That is why we are giving a significant priority to our cancer information service.

CANCER VACCINE DEVELOPMENT

Senator **Harkin**. Thank you very much, Dr. Broder.

I had one last question. I will submit it in writing, and it has to do with cancer research in pursuit of vaccine development, unless you have something that you can tell me on the prospects for effective use of vaccines, how are we proceeding on that?

Dr. **Broder**. Sir, this spring we are holding a special workshop to deal with issue of vaccines for cancer. I think it is a doable project. We have a wealth of ideas in this area, and we will make it a significant priority.

CLOSING OF THE CARDIAC SURGERY UNIT

Senator **Harkin**. Appreciate that.

Dr. Lenfant, one area that—well, first of all, let me ask you about this. I understand you have decided to close the heart surgery unit at the Warren G. Magnuson Clinical Center. Can you tell us about your decision to close the unit and how do you intend to use the $10 million in savings?

Dr. **Lenfant**. The decision to close our cardiac surgery unit resulted from several factors. First of all, being the changing nature of the cardiology program at the Institute. The emphasis is shifting from a purely clinical research to using molecular and cellular biology approaches. This has resulted in a decrease in the number of patients who are in need of surgery within our research program.

The second issue is one which was somewhat indirectly touched on in the previous questions to Dr. Raub. We have had two operating surgeons but one retired at the beginning of this month. Recruiting an experienced, senior cardiac surgeon within the Federal pay structure makes it very difficult.

I have to say that we did find young cardiac surgeons who might be interested in coming to NIH, but they made it very clear that it would be for a limited period of time. We did not feel that it would be to our advantage or benefit our program, to have to recruit continuously for a new cardiac surgeon.

All this happened in the context of emerging new research priorities at the Institute; priorities which we wanted to fit and develop within a set, fixed budget. These priorities are cardiac energetics, which is a way of looking at noninvasive diagnosis of cardiovascular disease. We are also developing a program in bone marrow transplantations and as Dr. Broder alluded to earlier, we have a program of genetic transfer and genetic therapy which is being initiated as well.

The cost of the cardiac surgery program, cost to the NIH Clinical Center, was $9.7 million last year. You can look at this cost as being made up of two components: one which is the cost of the surgery itself, the anesthesiologist, the blood bank, the access to the surgery room and other items, which are paid to a contract that the clinical center has to provide these services.

These costs will be eliminated by phasing out the cardiac surgery program, and we expect that they are in the order of $3 to $3.5 million a year.

The balance between the total and what I've just mentioned, are really costs which are intrinsic to the operation of the clinical center. These are the nurses, the overhead, the costs of common services and so on. Instead of having these nurses working on the cardiac surgery program, they are going to be shifted to other programs of the Institute such as genetic transfer, genetic therapy, or bone marrow transplantation.

So briefly, and I could amplify that in the record if you want, this is what we intend to do.

Senator **Harkin**. I appreciate that. Dr. Lenfant, I have a letter from you dated January 30, on this subject, and if you have no objection I will make that a part of the hearing record.

[The letter follows:]

LETTER FROM DR. CLAUDE LENFANT

January 30, 1990

The Honorable Tom Harkin
Chairman, Subcommittee on Labor, Health and Human Services
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

In preparation for the upcoming FY 1991 appropriations hearings, I recently met with Mr. Mike Stevens and Mr. Mike Hall to review with them topical issues and policy concerns pertinent to the hearings. One of the topics that we discussed concerned important changes in our intramural research program; specifically the phasing out of cardiac surgery services at the Clinical Center and increased emphases in other areas of our clinical research program. Because of your continuing interest and support of Heart, Lung and Blood research programs, it was suggested that I write to inform you of these significant developments. I am also sending Congressman William Natcher a letter identical to this one.

For many years the National Heart, Lung, and Blood Institute (NHLBI) has maintained a cardiac surgery unit within its Division of Intramural Research to support the cardiology research program. After considerable deliberation, it was determined to be in the best interest of the government, and, the intramural research program, to phase out the NHLBI Cardiac Surgery Branch and procure surgical support off-site. This decision was made by me, as Director for the Institute, after advice and recommendations from the Director, Division of Intramural Research, the appropriate Clinical Branch Chiefs, and senior staff of the Institute. This was also discussed with the Acting Director, NIH and the Assistant Secretary for Health, who have supported this decision.

The decision to phase out the Cardiac Surgery Branch was based on three major factors: (a) the changing nature of the cardiology research program; (b) the inability of the Federal Government to recruit and maintain a permanent cadre of qualified cardiac surgeons; and (c) the need to meet program priorities within budget constraints.

a. Changing nature of the cardiology research program

From an historical perspective, the NHLBI Cardiac Surgery Branch has made outstanding contributions to the fields of clinical surgery and surgery research. This was especially true in the areas of valve replacement procedures and hypertrophic cardiomyopathy. Cardiac surgery has always been essential and integral to the Institute's Cardiology Branch research program in providing an emergency back-up for invasive cardiology research procedures such as angioplasties.

However, currently the field of cardiology and cardiac surgery has advanced to the point that many of these procedures have now been accepted as standard clinical practice. The research of the Cardiology Branch is now evolving from purely clinical approaches involving invasive cardiology to new, molecular biology approaches for the treatment of cardiac disease. For these reasons the Institute's intramural invasive cardiology research program is being completely phased out, and no more angioplasties will be performed at the NIH Clinical Center.

As a result of these changes in the cardiac research program, the number of patients requiring cardiac surgery is expected to decrease significantly. Last year there were approximately 200 cardiac surgery patients. We expect about 155 patients this year with about a 30 percent or more decrease expected over the next year or two. The majority of the patients requiring cardiac surgery in the future will not be involved in ongoing research protocols, but will be former patients in need of clinical service such as valve replacements or coronary artery surgery. This routine clinical care can be performed at almost any hospital with a surgical facility. A small group of patients, approximately 50 per year, will be part of an ongoing hypertrophic cardiomyopathy research protocol.

b. Inability to recruit and maintain a permanent cadre of qualified surgeons

Currently, there are only two operating surgeons on board, one of whom will retire in February 1990. While there is an excellent group of 2-year surgery associates on board, it has become increasingly difficult to recruit a permanent cadre of qualified surgeons. One reason is the limited volume and nature of the surgery to be performed. Another is that the Federal pay scale cannot begin to compete with the pay scale of private hospitals and the potential earnings from private practice for board certified cardiac surgeons. Thus without the assurance of being able to recruit and retain senior surgeons, it is not possible to carry out a viable surgery unit to support cardiology research.

c. Program priorities and budget constraints

The clinical program of the NHLBI requires the commitment of a significant portion of the Institute's intramural resources. The hospital support costs for activities such as nursing support, critical care medicine, anesthesiology, pharmaceutical, and diagnostic radiology and nuclear medicine totaled approximately $27 million in FY 1989. More than one-third of this amount, about $10 million, was directly attributable to the maintenance of the cardiac surgery program. Given the changing nature of the cardiac research program, the relatively small number of patients and limited types of cardiac surgery being performed, and the resource needs of other intramural research programs, the NHLBI can no longer justify this level of support.

In the past year, the NHLBI has made extraordinary advances in the intramural research program and we are now faced with the challenge of moving these advances to the bedside by enhancing our clinical research program. This year has seen the emergence of gene therapy and gene transfer technology as a national health research priority. NHLBI scientists have successfully completed the first genetic transfer in humans in history, and expanded clinical trials are needed now so that this technology can ultimately be available to treat thousands of patients with genetic and non-genetic diseases.

Closely related to this is the need for a bone marrow transplantation unit in the Clinical Center. NHLBI is already responsible for the National Bone Marrow Donor Program. As part of our Blood Resources Education Program, we have initiated an education program for bone marrow transplantation to increase understanding of this program and improve donor recruitment. The transplantation unit in the Clinical Center is needed to enhance our research effort so that this therapy may be available to wider spectrum of diseases. The transplant unit will be initiated as part of the expansion of our clinical hematology program. In addition, research is needed to develop alternative serological tests and new molecular testing methodology to help increase the number of minorities in the donor pool.

Another important clinical initiative is in the area of Cardiac Energetics. As a result of funds provided in FY 1989 appropriation, a new facility will soon be completed, and important clinical studies will be initiated to help us understand how the heart actually functions at the cellular and molecular level. This knowledge will lead to new, noninvasive diagnostic and advanced new treatment methodologies.

The decision to phase out on-site cardiac surgery will allow the redirection of finite resources to support these new, high priority clinical research programs.

NHLBI is currently in the process of establishing an agreement for surgical services with one or more of the leading facilities in the Washington, D.C. area. This arrangement will permit us to continue to provide the finest quality care for those cardiac patients that might require surgery as part of their follow-up care and for emergencies. A close working relationship between our physicians and the surgeons at the local hospital will ensure consistent care of the highest quality. The actual closing of the cardiac surgery services in the Clinical Center is planned for July 1, 1990.

We are making every possible effort to make this a smooth transition and to ensure the best possible care for our cardiac patients. We will continue to evaluate patients in the Cardiology Branch and provide medical treatment at the Clinical Center. We will also continue the outpatient clinic for patients who have had cardiac surgery.

I hope this information is helpful and I will be pleased to provide any further information. I want to take this opportunity to again express our appreciation for your continuing interest and support of the NHLBI research programs.

Sincerely yours,

Claude Lenfant, M.D.
Director

CONGRESSIONAL INTEREST

Dr. **Lenfant**. Yes; of course. I should tell you, Mr. Chairman, that there has been considerable congressional interest on this issue. I have received to date, perhaps 100 letters from Members of Congress, about this matter.

The question comes from previous patients who have been patients in the Institute. You may be interested to know that we have established provisions to take care of these patients. First of all, we are going to keep our clinic open so these patients can continue to receive appropriate advice and care.

Now, if these patients are in need of further surgery, we also have additional provisions to the effect that if these patients do not have a third party to cover the cost of this additional surgery, we will take care of that in one of the surrounding hospitals in the Washington area.

NATIONAL CHOLESTEROL EDUCATION PROGRAM

Senator **Harkin**. You operate a number of education programs at an expense of approximately $6 million a year.

Dr. **Lenfant**. Yes.

Senator **Harkin**. I want to compliment you on your pursuit and support of these education programs. It is kind of difficult to find exactly what you spend because it is buried in the management contract line item.

I just want to cover one element of that, and that is on the cholesterol education program. It seems like everyday you open the newspaper, and it is one way and it is the other. You know, oat bran helps and now it does not. Then there is something that helps and something does not.

I have to tell you, I follow it very carefully. I have had an ongoing problem with this and have been battling it for several years, almost 10 now I guess, and as closely as I pay attention to it, I get confused.

How does the public out there know what to think? This whole area of cholesterol and reducing the cholesterol levels is one that is just very confusing. How are we going to get over this? And how are we going to get the adequate and correct information that people need to adequately protect themselves from high cholesterol levels?

Dr. LENFANT. I do recognize that lately, there has been some controversies with regard to our National Cholesterol Education Program. I think this has confused some of the public, but from surveys and assessments which we have made, I would say a very small fraction of the public has been confused by that.

The problem, however, is that those who are most confused are those who should pay more attention to their blood cholesterol level.

Senator HARKIN. Well, count me in that small fraction. [Laughter.]

Dr. LENFANT. The confusion is mostly in those who are taking medicine to lower their cholesterol. That is the issue that was raised in Mr. Moore's article in the Atlantic Monthly. It did question the association of high cholesterol with coronary heart disease, and for this reason, it did question the justification for a full-fledged campaign against cholesterol.

We believe that it was a very one-sided description of the scientific evidence, and this article really ignored a great amount of evidence which is very clear and most informative.

I also want to say that this cholesterol control program we have here in the United States, is also an international activity. There are indeed 16 or 17 other countries which have similar programs.

In this country alone we have 35 or 36 professional organizations which are also backing it up.

The bottom line is that clearly not all the evidence is in hand. There are still a number of questions that need to be addressed, but this does not eliminate the value and the importance of the scientific evidence which currently exists and is in support of our program.

In order to avoid confusing the public, I think we have to provide messages which are very clear and I think we have to debate, the counterarguments which have been presented. The bottom line is that if you look at the statistics which I presented to you earlier, I would say that something right must be happening.

Senator HARKIN. Let me just speak again from the layman's standpoint. We are not confused about the Atlantic Monthly article. I think the guy is way off base. I looked at his credentials. I see no scientific basis whatsoever for what he wrote, other than he made a big name for himself and he got a lot of publicity because everyone is concerned about this area.

The confusion comes in the area of exactly what to do about your cholesterol level and how to bring it down. What is required, perhaps even in the nonmedical area?

When you go to the grocery store, you go up and down the aisles now and see all these things, about reduced cholesterol. You wonder: Does it really work or not?

People need some better information on what kind of diet is best to keep their cholesterol levels at the lowest possible.

Dr. **Lenfant**. I would agree with you. We are greatly concerned with the fact that, for instance, the food industry advertises and emphasizes products with low cholesterol, but quite often, with complete disregard of the amount of saturated fats that are in these food products. Of course, as we all know, it is the saturated fat which is the most important element.

We are trying to correct this situation. We work with the FDA. Unfortunately, at this point in time, there are no food labeling regulations which are established, although I understand they are being developed.

Senator **Harkin**. We will work on that this year, and hopefully we will have something through this year on a standard labeling for the FDA. That comes through another committee, but any advice you could give us on that would be a great help to us.

Dr. **Lenfant**. I should tell you that 1 week from today, at the next meeting of the National Cholesterol Education Program, we expect that a report which addresses a population-based strategy for the control of cholesterol and coronary heart disease will be released. You may recall, Mr. Chairman, that a couple of years ago we did release a report which was directed to high-risk subjects. The one that is going to appear in a week is population based, that is, it will provide some advice which can be used by nearly all people.

If you wish, I would be pleased to send you a copy of this report when it is published.

Senator **Harkin**. When is that, a week from today?

Dr. **Lenfant**. Yes; and I should say, that this report will be endorsed by approximately 35 or 36 professional societies of this country.

Senator **Harkin**. I certainly hope we get some publicity out on it, too.

Dr. **Lenfant**. It will. We have a press conference which is scheduled to announce the release of this report.

Senator **Harkin**. I look forward to that and if you have more in-depth information, I would like to see that also.

FLUORIDE SAFETY

Dr. Löe, I grew up in a rural area drinking well water that was not fluoridated. I did not see a dentist until I was in high school. So much for health care in rural areas. By that time I needed a lot of dental work like everybody did in that area.

My kids, one about to enter high school and one still in grade school, have been drinking fluoridated water ever since they were old enough to drink water. They have never had any dental problems. They go to see a dentist and they have never had any cavities or anything.

Now, clinical trials on the health effects of fluoride have raised some new issues on the safety of fluoride. I will not go through all the studies and the groups of rats and how much they were administered. What can you tell us about the health effects of fluoride in drinking water?

Should we be concerned or do the health benefits far outweigh any of the---

Dr. **LÖE**. I think what you have said so far is recounting the dramatic story of the effect of fluoridation in this country, and I have reported on that several times in these hearings. It is a fact that we have accomplished in the United States what has not been accomplished in any other country—reduction in tooth decay to very low levels in the young population.

The discussion of the side effects of fluorides has been going on since the beginning of fluoridation; you probably remember the discussion, both in the press and in these chambers, when fluoridation was initiated in the 1940's and 1950's.

Senator **HARKIN**. It was a Communist plot.

Dr. **LÖE**. It was a Communist plot and a few other things that were mentioned for good measure.

However, in the 1970's Congress mandated a new study of the side effects of fluorides. The National Toxicology Program has now produced a preliminary set of data that would appear to indicate that in rats, with high dosage levels, you will find some very rare bone cancers that we call osteosarcomas.

This has occurred in five rats out of about 540 male rats. Nothing in the female rats but only in the male rats; one at midlevel doses of fluoride and four at the highest dosage, which is approximately 80 times the level that is recommended by the Public Health Service for water fluoridation.

Well, the short story here is, of course, that these are preliminary data. The data will be going through a process of peer review and interpretation before a conclusion is reached on the matter. In the meantime, at both the Department, through the Secretary and Assistant Secretary for Health, as well as at the NIH level, a process has been established through which we will analyze the data and provide the public with information.

We do not think there is any reason for panic at this point. The ultimate evidence would have to come from human studies and the National Cancer Institute has already studied the relationship between cancer and naturally and artificially fluoridated waters.

That occurred back in the 1970's. From that comprehensive study there was no indication that there was a relationship or any correlation between the amount of fluoride in some of the communities that had natural fluoridation or in other counties that had optimal fluoride in the waters, and the prevalence and incidence of cancer.

The Cancer Institute is already involved in a new study to refine their methodology and to bring about an analysis of the various levels of fluoride intake in some communities, and the prevalence of these special bone cancers that have been reported.

One of the problems with this is that osteosarcoma is a very rare cancer. No more than 700 or 800 cases occur per year, and it could be a very difficult to prove either way, because of the low levels of this cancer.

But the "C" word has been spoken, and it is going to be a difficult thing to continue to talk about fluoridation out there if we do not provide the correct information to the public.

FLUORIDATION

Senator **Harkin**. Dr. Broder, you were quoted I think in the paper as saying that there was no evidence in the past to link these two and you did not see any evidence in these studies that would basically link them.

I guess it did not occur in mice, it did not occur in females——

Dr. **Löe**. That is correct.

Dr. **Broder**. Sir, the thing I would like to say is that in the mid-1970's we examined this issue very carefully, with our Division of Cancer Etiology, and in effect, they did what amounted to, a county-by-county analyses of cancer statistics, both with natural fluoridation and also before and after studies of counties after fluoridation occurred.

In those studies in the mid-1970's there was no documented association between any increase of incidence or death rate of cancer, specifically bone cancers and cancers of the mouth were examined.

In addition, there are a number of other studies from other countries, including Great Britain, New Zealand, Australia and so on, which support this particular concept. There are many countries that have examined this issue and found that there was no association.

However, we do treat these results seriously, and we feel that the best way of dealing with this issue is with facts and informed opinions. We are re-evaluating the data collected from the mid-1970's, and I have directed the Division of Cancer Etiology to submit a progress report with their findings by the summer of this year, June if possible. We hope, at that point, to make those statistics and followup information available to the NIH community and to the committee.

Senator **Harkin**. Thank you.

Dr. Raub?

Dr. **Raub**. May I just make an addendum, to stress how carefully coordinated this overall effort is. As a scientific organization, we have an obligation not to prejudge information, to let the data tell us what it has to say.

On the other hand, we have an obligation to evaluate it thoroughly. As Dr. Löe indicated, the first step here is for the National Toxicology Program, which is part of the National Institute of Environmental Health Sciences, to complete its detailed analyses of the rat and mouse data. We hope to have that data before the end of April of this year.

As Dr. Broder indicated, the Cancer Institute will be updating its analyses from human epidemiology and have the latest information on that. Dr. Löe and his colleagues are updating the information with respect to public health impacts and consequences. All of that will be synthesized in a multistep process through the Public Health Service to ensure that we make the most thorough and balanced set of public statements when this is completed.

PEDIATRIC AIDS

Senator HARKIN. I am glad to hear that. Dr. Fauci, I do not mean to go over all the AIDS questions that Senator Bumpers asked. I think he covered that quite well. I want to focus on one small area very briefly and that is pediatric AIDS.

I became interested in that this year while I was reading the findings that some children who have HIV infected mothers are born HIV positive and some are not. Some children who take their mother's milk get HIV; some do not. Some of the manifestations of the illness that are in adults do not occur in children and vice versa.

It seems to me to be a very fertile area for research trying to figure out why this is happening in some and not in others. I just wonder what you can tell us about the area of pediatric AIDS. Are we doing enough in that? Do we need to do more?

I have a specific question about testing drugs. You do adults; you have to go through the whole procedure again through FDA for children. Should we change that? What is happening in that area?

So just address yourself to the full area of pediatric AIDS.

Dr. FAUCI. I will very briefly address those issues, Mr. Chairman.

With regard to the work on pediatric AIDS, there are several areas, including the areas in fundamental research on the response of the developing human to HIV infection versus the adult.

There is absolutely no question that some of the manifestations of HIV infection in a child or an infant is significantly different than that in an adult. Particularly, for example, in the area of lung disease. The interstitial pneumonitis that children get that adults rarely get is unrelated to any other infections.

The profound effect of the virus on the developing nervous system is clearly seen in the infant. Even though you do get severe neuropsychiatric problems in an adult, the relative proportion and severity in infants is very clear. The susceptibility to bacterial infections because of problems with antibody responses in infants is another area which needs exploring. Those are just three examples of the important areas that need to be further investigated.

Over the past couple of years we have intensified our efforts in pediatric AIDS research in fiscal year 1991, we have $81 million, up from just a few years ago of $37 million in pediatric AIDS research. But there is still more that needs to be done.

With regard to clinical trials, right now out of the 47 clinical trial units in our AIDS clinical trial group, 15 now are devoted solely to pediatric AIDS, in addition to several of the adult trials which have a pediatric component. And over the past 2 years, we have intensified our collaborative effort with the Child Health Institute in which we are utilizing each other's expertise—they, in their pediatric centers and we with our AIDS clinical trials unit experience.

So there is a lot of activity, but I must say again that there is more which needs to be done because it is a problem if one looks at the demography of HIV infection. Pediatric AIDS is going to intensify over the next few years because the rate of new cases of HIV infection. The rates are disproportionately rising now among IV drug users and their sexual partners, and women and children born of those unions.

So right now what we are going to be seeing are relatively higher rates of infection among these groups than among the classic groups that we have seen in the early and mid-1980's, namely the male homosexual populations.

So it is a problem that is not going to go away. It is going to get worse in the 1990's.

With regard to your question about drugs that are tested in children, the philosophy in the past is rapidly changing. Until recently, it has been standard practice in our clinical trials to never test a drug for a disease that affects both adults and children, in a child or an infant. Drugs were tested in children only after being thoroughly tested and proven effective and safe in adults.

And likewise, even after it had been proven to be safe and effective in an adult, it would not be unusual to go back and do the entire clinical trial over again in a child.

This philosophy has changed, because we do not have that long period of time with HIV infected infants and children.

What we have seen over the past couple of years now is essentially simultaneous studies of the same drug in adults as well as in children and in infants. This process reduced by at least a couple of years the delay that we initially experienced with the availability of AZT, for example, for infants and children, which just this past year has been granted a treatment IND for infants from over 3 months old to 12 years old.

NIAID CLINICAL TRIALS

Senator **Harkin**. Of the 34 drugs that are in clinical trials, how many of those are being done simultaneously?

Dr. **Fauci**. There are several. There are DDI studies, AZT studies, and intravenous immunoglobulin studies. The predominant being the DDI and the AZT studies in children.

It is more important and it has happened over these past few months that at least we have a drug that can be standard treatment for the children and that is what the treatment IND for AZT has allowed. Before, unless you were on a clinical trial and you were a child, you had access to absolutely no drug.

Senator **Harkin**. Should we expand that? It sounds like you are just doing a few out of the 34.

Dr. **Fauci**. Yes; right now, as new drugs come on, the philosophy has changed. As they go on to clinical trials, they will be given to both children and adults on a clinical trial.

Senator **Harkin**. Are you doing this in other areas? Should we be doing it in other areas, doing it simultaneously, rather than doing one and then going to the other?

Dr. **Broder**. The philosophy has emerged and has been heading toward the area of not having very long delays. There was an era in which a drug had to have every I dotted and every T crossed before it could be given to children with a lethal disorder, and that philosophy has changed.

In cancer-related research and in the AIDS-related research in children, which the Cancer Institute also supports, the philosophy has been to try to move into as much of a transition as possible. We think that there is an emerging consensus that the process has to go faster. We are very pleased, in fact proud, of the role that the NIH has had in making sure that this philosophy comes about.

USE OF FETAL TISSUE

Senator HARKIN. Dr. Fauci, in an October 1989 speech you discussed the theoretical possibility of using fetal cells to reconstitute the immune system of AIDS patients.

Unlike adult cell transplantations, I guess fetal cells would not provoke tissue rejection problems. Attempts to reconstitute the immune system of AIDS patients using bone marrow transplants from the patient's identical twin have not been successful.

Now, we discussed earlier with Dr. Raub about the ban on Federal funding for transplantation research using fetal tissue.

That ban would affect this type of research. Is that right or not?

Dr. FAUCI. Yes; I was talking about a hypothetical situation. In fact the context in which I mentioned that was based on an ongoing study; trying to look at what the earliest cell in the development of the immune system is that could be infected with HIV.

We are investigating whether or not early precursor cells can be infected, and what the hypothetical situation would be that if, in fact, those cells were infected. We would then ask what the best possible avenue of research to take would be, and determine if you could in fact transplant back into an individual those precursor cells which had been depleted, using fetal tissue of the immune system.

Senator HARKIN. You cannot do that.

Dr. FAUCI. Now, if in fact that theoretical situation came to pass, under the current moratorium of transplanting fetal tissue into humans from induced abortion, that would fall under the moratorium, if indeed that situation occurred.

Senator HARKIN. Is there any foreign research being done using this process?

Dr. FAUCI. To my knowledge right now, there are a couple of anecdotal cases of putting in fetal thymus tissue and fetal liver tissue, but no large studies to my knowledge.

Senator HARKIN. Is any other research being done someplace else to get around the ban in this country? Are you aware of any?

Dr. FAUCI. I think the important thing to establish, Mr. Chairman, first of all, is what we are actively doing in the laboratory right now that is, attempting to determine if there is a scientific basis for that. Namely, is there infection of those early cells, and if there is, then you will have to replace them with transplantation.

But before you embark on a program to replace them, I think it is important to determine if in fact they have been depleted, and that is where we are in that state of research right now.

SUBCOMMITTEE RECESS

Senator **Harkin**. I thank you all very much for great testimony, and I also just want to thank you for all the wonderful work that you are doing out at NIH.

The subcommittee will stand in recess until 1:30 p.m., when we will hear from panel 3 and the rest of the Institutes.

[Whereupon, at 12:47 p.m., Tuesday, February 20, the subcommittee was recessed, to reconvene at 1:30 p.m., the same day.]

(Afternoon Session, 1:30 p.m., Tuesday, February 20, 1990)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases

STATEMENT OF DR. PHILLIP GORDEN, DIRECTOR

SUMMARY STATEMENT

Senator Harkin. The Appropriations Subcommittee on Labor, Health and Human Services, and Education, and Related Agencies will come to order.

This afternoon we have our third panel: In addition to Dr. Raub; Dr. Phillip Gorden, Director of the National Institute of Diabetes and Digestive and Kidney Diseases; Dr. Duane Alexander, Director of the National Institute of Child Health and Human Development; Dr. David Rall, Director of the National Institute of Environmental Health Sciences; and Dr. Phillip Schambra, Director of the John E. Fogarty International Center

Again, we will just go down that list in the order in which I called it.

First, Dr. Gorden, glad to have you with us. I notice that your Institute celebrates its 40th anniversary this year. We look forward to see what progress you are making. Your request for 1991 is $605.35 million is what my figures show, or about a 4.11 percent increase.

So welcome to the subcommittee and we will try to go through the different things and we will go back to questioning because some of the questions go back and forth and they are interrelated.

Dr. Gorden, please proceed. All of your statements will be made a part of the record in their entirety and if you would briefly summarize I would sure appreciate it.

Dr. Gorden. Thank you, Mr. Chairman. This is a special year for us as it is our 40th anniversary. We were signed into law by President Harry Truman in August 1950.

In recognition of this milestone I would like to focus on a few examples of the many contributions of NIDDK's basic and applied research to clinical medicine.

One of the crowning research achievements of the past year is the discovery of the gene that causes cystic fibrosis. Discovery of the cystic fibrosis gene, however, would have been impossible without the earlier Nobel Prize winning research rooted in the NIDDK. The identification of the first enzyme known that could copy DNA, the unraveling of the code by which DNA translates itself into protein-building blocks of the body, and the discovery of the mechanism used by proteins to fold themselves into their proper shapes for activities are all three Nobel Prize winning endeavors.

Forty years ago when this Institute was founded, diabetes was an enigma. Today, we know that there are fundamentally two forms of diabetes: type I or insulin dependent diabetes is an immunologic abnormality where the body's immune system attacks the insulin-producing cells.

We know that a particular gene controls susceptibility to that disease; that is, a particular gene confers either protection or susceptibility to the disease. This gene is not sufficient to cause the disease, but is necessary.

The more prevalent form of diabetes, type II diabetes, or noninsulin dependent diabetes, is also a genetic disease. In this disease, in identical twins, there is a 90-percent chance that if one twin has diabetes the other twin will have diabetes within 5 years. That is a very powerful genetic statement.

At the present time we do not know what genes are involved in this disease, but it is a very important pursuit of the Institute.

Today the clinical management of diabetes is vastly improved. Diabetes can be diagnosed and treated earlier. Recombinant insulin is now available for treatment, a major accomplishment of the biotechnology industry.

Patients can conveniently test their blood sugars at home or at work. Research is also underway on implantable insulin pumps for improvement of the administration of insulin.

End-stage renal disease is another area of major achievement. When the NIDDK was founded in 1950, patients routinely died within days of kidney failure. Now, dialysis and transplantation have completely altered the outlook for end-stage renal disease patients. In addition, a new drug called erythropoietin combats the anemia of dialysis patients, enabling them to return to work and lead more fully productive lives.

Remarkable research advances have likewise been seen in liver disease. Forty years ago liver failure was an absolute death sentence. Today, two-thirds of transplant recipients survive 1 to 3 years after transplantation, and the long-term survival rate continues to improve. The NIDDK has contributed to the development of potent immunosuppressive drugs and organ preservation solutions that have been essential to these advances.

At the same time, we recognize that dialysis and organ transplantation are incomplete measures, and we remain firmly committed to research aimed at preventing end-stage kidney and liver diseases.

Important contributions have been made recently in type B and type C hepatitis in terms of specific therapies.

PREPARED STATEMENT

These examples of progress underscore the crucial importance of the Institute's 40 year record of achievement in basic and applied research, which has laid the foundation for landmark advances in biotechnology, drug and device development, and clinical procedures.

Mr. Chairman, the 1991 budget request for the National Institute of Diabetes and Digestive and Kidney Diseases is $605,349,000.

Thank you.

[The statement follows:]

STATEMENT OF DR. PHILLIP GORDEN

I am particularly pleased to be able to testify before the Subcommittee in 1990, the year that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) celebrates its 40th anniversary. In recognition of this milestone, I would like to focus on four research areas in which this Institute has made major contributions during the past 40 years: cystic fibrosis, diabetes, kidney disease, and liver disease. The progress in these areas exemplifies the crucial importance of this Institute's solid basic research, which has laid the foundation for landmark advances in biotechnology, drug and device development, and clinical procedures.

For 40 years, NIDDK has been in the vanguard of research on cystic fibrosis, a disease that painfully strikes down and kills children and young adults. Thus it is with a profound sense of accomplishment that we can report the recent discovery of the defective gene and protein responsible for the most prevalent form of this dread disease. This is one of the crowning research achievements of the past year, and the culmination of decades of basic research supported through the collective efforts of several NIH institutes, the Howard Hughes Medical Institute, and the CF Foundation.

Prior to 1950--the year this Institute was created--cystic fibrosis was one of the most hopeless diseases known. At that time, Arthur Kornberg was a brilliant young biochemist working in a laboratory at the NIH that is now part of the NIDDK intramural research program. In 1956, he discovered the first enzyme known that could copy DNA, the cellular material that is the key to modern molecular biology and genetics. At the time, no one thought this finding had any bearing on cystic fibrosis, but in many ways, Kornberg's work was a precursor of today's recombinant DNA technology, which enabled the discovery of the cystic fibrosis gene. Kornberg went on to receive the Nobel prize for his seminal achievement--the first in a series of Nobel laureates who have roots in the NIDDK.

Another important benchmark in CF research was in 1953, just three years after this Institute was formed. Paul Di Sant'Agnese, an NIDDK scientist, discovered an abnormality in the sweat of cystic fibrosis patients. This advance led to the first diagnostic test for this disease. In the following years, NIDDK researchers were at the hub of the revolution in molecular biology that later proved essential to the discovery of the CF gene. Marshall Nirenberg spearheaded the unravelling of the code through which DNA translates itself into the protein building blocks of the body. Christian Anfinsen uncovered the mechanism used by proteins to fold themselves into their proper shapes. These scientists won Nobel prizes for their ground-breaking work--work that needed to be accomplished before the secret of cystic fibrosis could be revealed.

Then, in 1983, NIDDK-supported researchers, who were engaged in pioneering studies of cell membranes, discovered the first fundamental molecular defect in cystic fibrosis. They found that the channels transporting salts through cell membranes in CF patients did not work correctly. These studies helped to explain the debilitating mucus that impedes the proper functioning of the lungs, the digestive system and the pancreas in CF patients.

In 1987, NIDDK grantees pinpointed the location of the CF gene to a specific chromosome, and research teams around the world began to narrow their search. Finally, in 1989, a team of NIDDK-supported American and Canadian scientists reported how they had "walked" and "jumped" up and down the chromosome to pinpoint the gene in an approach called "reverse" genetics. In conventional genetics scientists find the defective protein first and work from there to find the gene. In "reverse" genetics, they find the gene first. For the CF researchers, this approach was likened to looking for a broken faucet in a house somewhere in the United States, without the benefit of road maps. Fortunately, with the tools of modern molecular biology, they succeeded.

The discovery of the CF gene rests solidly on years of prior work in cell biology that has developed in a parallel track with molecular genetics. Such fundamental, untargeted research has relied for decades upon the support of the Congress and the public. Now, armed with the CF gene, researchers can design membrane study systems to find ways to make the defective protein work correctly, and ultimately, to seek ways to correct the genetic defect in CF patients through gene therapy. We used to call cystic fibrosis a "disease in search of an idea." In 1990, it is a disease for which there is renewed hope and intense research momentum.

The achievement record in diabetes research is similarly impressive, in terms of understanding and managing this disease. Forty years ago, when this Institute was founded, diabetes was an enigma. The discovery of insulin in the 1920s helped prolong the lives of diabetics, but we understood very little of the disease process and of the severe complications that plagued patients: heart and nerve damage, amputations, and blindness. Over the past 40 years, our ability to comprehend and manage diabetes has changed dramatically. Today, we know that diabetes, which affects an estimated 11-12 million Americans, isn't just one disease with one cause. We know that in Type I, or insulin-dependent diabetes, the body's immune system mistakenly destroys the special group of cells that produce insulin. There is a major genetic risk factor for this condition--and we know at least one error in DNA that marks this risk. For Type II diabetes, we know that resistance to insulin is the underlying problem. Genetics plays a role in causing this disease, but life-style risk factors such as obesity also are extremely important. We also know that Type II diabetes disproportionately affects the Black, Hispanic, Native American, Alaska Native and Native Hawaiian populations.

Major advances have also been attained in improved diagnosis and clinical management of diabetes. Today, if you have diabetes, the chances are greater that you have been diagnosed early. This is important in receiving proper medical advice and treatment, especially for anticipating and treating diabetic complications. While insulin shots are still part of the daily routine of many patients, recombinant human insulin is now available as a result of biotechnology. This drug has prevented problems of insulin shortage, contamination, and immune reaction related to the animal products that were previously the only source of insulin. Today, patients can also conveniently test their blood at home or work to see if they need more insulin --making it far less likely that they will take too much and risk a coma. Recently, the development of an implantable insulin pump has progressed to successful testing for an 18-month period. When the appropriate research on this device is concluded, the pump will offer patients a treatment option that frees them from daily shots, although they must continue to monitor their blood glucose levels. These clinical management techniques are important to patients and their families, empowering them to take control of their disease and live more productive and unencumbered lives.

Another critical advance in diabetes has been the ability to test patients for molecules in their blood that form when glucose levels stay too high over time. This is vital information in monitoring the treatment of a diabetic patient--to know when that person is succeeding in controlling glucose levels, and when he or she needs help. The NIDDK is sponsoring a large multicenter clinical trial to answer the single most important clinical question in diabetes today--whether long-term careful control of blood glucose levels as close to normal as possible can prevent, delay, or ameliorate the development of the blood-vessel damage that is a major complication of diabetes.

During the past 40 years of this Institute's achievements, another example of major research progress has been end stage renal disease (ESRD). When the NIDDK was founded in 1950, there was nothing to offer as a treatment: patients often died within days or weeks of acute kidney failure. Now, three major advances have completely altered the outlook for ESRD patients. The first is dialysis, which can successfully maintain even those patients whose kidneys are useless. Initially, this life-saving procedure was cumbersome and time-consuming. Today, however, kidney dialysis can be performed comfortably and relatively quickly in hospitals, dialysis centers, and at home.

A second advance in ESRD is the approval by the Food and Drug Administration of a new drug that combats the anemia of dialysis patients and enables many of them to return to work and lead full and productive lives. This drug, called erythropoietin, was developed through the new techniques of biotechnology, with research supported in part by this Institute. The drug stimulates the production of red blood cells, thereby allowing dialysis patients to overcome the anemia and exhaustion that often afflict them.

A third advance in ESRD is kidney transplantation. About 50 percent of ESRD patients will eventually receive a transplant. The success rates for this procedure have increased steadily during the years, with the one-year graft survival rate for a transplant from a living-related donor now approaching 90 percent. This Institute has contributed greatly to the development of new transplantation approaches by transplant surgeons and urologists. These advances have in turn helped the development of the nation's organ donor system, which provides needed organs for ESRD patients, as well as an opportunity for people to help each other in fighting disease.

This retrospective on the 40-year accomplishments of the NIDDK would be incomplete without a description of our efforts to combat liver failure. Forty years ago, liver failure was an absolute death sentence. Today, over two thirds of transplant recipients survive a year or more after transplantation and the long-term survival rate continues to improve. Transplantation as a treatment for liver disease has developed entirely during the history of the NIDDK, which for over 20 years has continuously supported one of the premiere researchers in the field, Dr. Thomas Starzl of the University of Pittsburgh.

New drugs and new surgical techniques have transformed liver transplantation from an experimental procedure to a successful treatment. The development of the immunosuppressant drug, cyclosporine, has played a key role in this progress. Recently, a new drug called FK-506 has demonstrated great promise for protecting against transplant rejection, but without the side effects of cyclosporine. Another central advance in liver transplantation has been the development, with NIDDK support, of a solution for preservation of donor organs until they can be transplanted. This solution has made it possible to maintain organs outside the body for much longer periods of time, thereby enabling greater use of available organs and better matches of donor and recipient. The solution is expected to improve graft viability in other forms of transplantation as well.

While kidney dialysis and the transplantation of kidneys and livers are life-saving therapies, we also have to remember that they are still "half-way" technologies that do not address the underlying causes of disease. For this reason, the NIDDK is firmly committed to pursuing research aimed at preventing these chronic and costly diseases. I'm pleased today to be able to report from the Institute's intramural program a recent major research advance in the treatment of liver disease. For the first time, a promising treatment has been discovered for Type C hepatitis, which accounts for the vast majority of the cases of post-transfusion hepatitis, and can cause cirrhosis followed by liver failure and transplantation. Fifty percent of patients with chronic hepatitis C showed a complete response when treated with recombinant alpha interferon administered in a randomized, controlled clinical trial. We are energetically pursuing this significant discovery in order to examine long-term responses and to evaluate the combined use of alpha interferon with other agents.

I have chosen today to present only a few major areas of research to illustrate the achievements our Institute has supported over most of its 40-year history. In looking to the future, I hope soon to be able to tell you more about other diseases that we are only just beginning to understand--diseases such as inflammatory bowel disease, interstitial cystitis, and polycystic kidney disease. We knew virtually nothing about these diseases 40 years ago. Now, they are being characterized, and research is under way to apply to these diseases the same techniques of molecular biology that have proven so successful in cystic fibrosis. We are also actively pursuing promising research leads on a wide range of other important public health problems such as osteoporosis and obesity.

The foresight of the Congress and the public in strongly supporting the work of the NIDDK during the past 40 years has resulted in major health advances for the huge population of Americans afflicted with chronic diseases. Your continued faith in our efforts and support for our mission can lead to improved health and well-being for millions more.

Mr. Chairman, the 1991 budget request for the National Institute of Diabetes and Digestive and Kidney Diseases favors basic research and totals $605,349,000. Thank you for this opportunity to testify.

BIOGRAPHY OF DR. PHILLIP GORDEN

December 22, 1934. Baldwyn, Mississippi. Married, two children.

Education: B.A., Vanderbilt University, Nashville, Tennessee, 1957; M.D., Vanderbilt University School of Medicine, Nashville, Tennessee, 1961.

Professional History: 1961-62, Intern, Yale University, New Haven, Connecticut. 1962-64, Assistant Resident, Yale University, New Haven, Connecticut. 1964-65, USPHS Clinical Fellow in Metabolism, Yale University, New Haven, Connecticut. 1965-66, USPHS Research Fellow in Metabolism, Yale University, New Haven, Connecticut. 1966-74, Senior Investigator, Clinical Endocrinology Branch, National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health. 1974-78, Senior Investigator, Diabetes Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1974-76, Clinical Director, National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health. 1976-78, Visiting Professor, Institute of Histology and Embryology, University of Geneva School of Medicine, Geneva, Switzerland. 1978-present, Chief, Section on Clinical and Cellular Biology, Diabetes Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1980-1986, Clinical Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1983-1989, Chief, Diabetes Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1986-present, Director, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

Professional Organizations: American College of Physicians, American Diabetes Association, American Federation of Clinical Research, American Society for Clinical Investigation, Endocrine Society, American Society for Cell Biology, Association of American Physicians, American Society for Biochemistry and Molecular Biology.

Honors, Awards: Alpha Omega Alpha Medical Fraternity, 1961. Doctor of Medicine (Honoris Causa) - University of Geneva, Geneva, Switzerland, 1986. Public Health Service Distinguished Service Medal, 1986. Public Health Service Commendation Medal, 1988.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Dr. Gorden, thank you very much. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

DIABETES IN NATIVE AMERICANS AND MINORITY POPULATIONS

Question. Dr. Gorden, your Institute is one of the few which has an intramural facility outside of the Washington metropolitan area. I understand that you have a facility in Phoenix, Arizona, so that you can work with the Pima Indians, who have an incredibly high incidence rate of diabetes. What are we learning as to why Native Americans and minority populations have such a higher incidence rate of diabetes?

Answer. The NIDDK Phoenix Epidemiology and Clinical Research Branch has been studying the Pima Indian population since 1963, and today is headquarters of the largest prospective study of diabetes mellitus anywhere in the world. Early studies of the Pima revealed that diabetes occurs in 50 percent of those aged 35 years and over, a rate 10-15 times as frequent as reported in the general U.S. population at that time. The Pima suffer almost exclusively from non-insulin dependent diabetes (NIDDM). Long-term studies have shown that many people do not just suddenly develop the high blood glucose levels characteristic of this disease, but for years exhibit a pattern of increasing insulin and glucose levels. Most people with this condition of impaired glucose tolerance go on to develop NIDDM. In the Pima, impaired glucose tolerance is caused by insulin resistance, which may be due to a single gene defect in this group. The NIDDK is pursuing genetic linkage studies to identify the responsible gene.

The Institute is also studying the relationship between obesity and diabetes. In the Pima, obesity appears to be a major risk factor for the development of diabetes. In addition, the chances of a child becoming obese appear to be increased if the mother was diabetic at the time of pregnancy. Studies at the Phoenix Branch have demonstrated individual differences in the rate at which people burn calories at rest, and that a low rate may predispose one to obesity.

Native Americans are not the only populations that suffer disproportionately from diabetes. The NIDDK has sponsored and participated in several conferences and workshops in the past two years that addressed Diabetes in the Black Population, Diabetes in Native Americans and Alaska Natives, and Diabetes in Hispanics. Black Americans of every age are at greater risk of developing diabetes than White Americans. Hispanics also show a disproportionate prevalence of diabetes, with fully one third of the group 65-74 years of age suffering from the disease. A recent report from the NIDDK to this committee on diabetes in Native Hawaiians, stated that the prevalence of the disease in Native Hawaiians on an age-adjusted basis is twice that seen in other ethnic groups in Hawaii. While the basis for the increased prevalence of diabetes in all these groups in unknown, the high prevalence of obesity appears to be one of the factors involved.

Kidney disease associated with NIDDM occurs much more frequently in Blacks than in Whites, but surprisingly, Blacks with end stage renal disease appear to survive better than Whites. NIDDK continues to study the genetics, disease process, risk factors, epidemiology, and possible interventions for control of diabetes. These efforts should result in improved well-being of minority populations that bear the burden of NIDDM.

DIABETES AND OBESITY

Question. What is the correlation between diabetes and obesity?

Answer. About 95 percent of all diabetics suffer from non-insulin dependent diabetes mellitus (NIDDM), a condition characterized in part by insulin resistance. Individuals who are 20 to 30 percent overweight are at an increased risk for NIDDM, and this risk accelerates with increased body weight. In addition, many minority populations that display a high prevalence of obesity also are disproportionately affected by NIDDM. Since most obese individuals are not diabetic, however, it is clear that some predisposing tendencies, perhaps genetic, must be involved in determining who will develop diabetes.

NIDDK-supported research is revealing NIDDM to be a disease that can result from errors in a host of metabolic steps including insulin secretion, insulin binding to cell receptors, the response of cell receptors to insulin, and the transport of glucose across cell membranes. Recent NIDDK-supported studies have provided direct evidence of the relation between obesity and NIDDM at the molecular level. A particular part of the insulin receptor, the enzyme tyrosine kinase, is necessary for the cell to exhibit a proper response to insulin. In many NIDDM patients the level of the tyrosine kinase enzyme is reduced. If NIDDM patients that are obese lose weight, however, this defect in the enzyme is largely reversed. This discovery provides a potential molecular rationale for attempts to influence the course of NIDDM through weight control.

Studies in the Pima Indian population at the NIDDK Phoenix Epidemiology and Clinical Research Branch are also aimed at unravelling the reasons behind the extraordinarily high prevalence of NIDDM and obesity in this population. It appears that, in the Pima, NIDDM may be linked to a single genetic defect, and it is also highly correlated with obesity. NIDDK-supported research on individual differences in resting metabolic rate among the Pima suggest that this may be a factor in determining obesity. Continuing research on the genetic and metabolic factors related to NIDDM in the Pima may elucidate the disease process in other groups.

END-STAGE RENAL DISEASE

Question. Dr. Gorden, as you know, we spend approximately $3 billion per year out of the medicare trust fund providing dialysis treatment for individuals with end-stage renal disease. What progress is being made to reduce the incidence of end-stage renal disease?

Answer. NIDDK has the principal responsibility at NIH for research into the causes, consequences, treatment and prevention of end-stage renal disease (ESRD). Our research directed at reducing the incidence of ESRD falls into two general categories: 1) identifying the causes; and 2) preventing the progression of renal disease, once it has been diagnosed.

We developed the United States Renal Data System to begin studies of the causes of ESRD as a first step in the direction of designing programs to reduce the incidence of end-stage renal disease. This system allows us to analyze data collected by the Health Care Financing Administration on all patients in the ESRD program. The first annual report was available in August 1989. This is the first comprehensive attempt to characterize the total ESRD population and to report on the incidence, prevalence, and mortality rates of renal disease by cause and treatment modality. Its goal is to identify opportunities for research into the causes and prevention of ESRD. One application of this database is the development of a new initiative entitled "Kidney Disease and Hypertension in Blacks". This initiative was based on the new finding that blacks have nearly a five fold overall greater incidence of ESRD, compared to the overall U.S. population, and that hypertension is the most common cause of ESRD in this group.

NIDDK has two clinical studies, in addition to a basic research effort, in the area of prevention of progression of renal disease. They fall into two general categories: 1) patients with kidney disease of diabetes mellitus (KDDM); and 2) patients with other forms of kidney disease.

The kidney disease in diabetes mellitus is the largest single cause of ESRD in the U.S. Basic scientific studies into the prevention of KDDM are being carried out by investigators supported under all of our mechanisms: investigator-initiated grants in both the kidney and diabetes divisions; a study of the Pima Indians under a contract; and basic scientific studies at a Boston-based George M. O'Brien center. Two clinical intervention studies, conducted by the Johns Hopkins University and by Rush Presbyterian-St. Lukes Hospital are evaluating the use of antihypertensive therapy to prevent or inhibit the progression of KDDM. In addition, the use of glucose control to prevent KDDM is being evaluated in the multicenter Diabetes Complications and Control Clinical Trial.

The prevention of progression in patients with various forms of renal disease, including diabetes mellitus, is being evaluated in a 15-center clinical trial. This trial, the Modification of Diet in Renal Disease study (MDRD), is addressing the question of whether dietary protein restriction and blood pressure control can impede the progression of renal disease. It has just finished the first of a three year clinical phase. It will be completed in 1993. This trial, a collaborative effort between the NIH and HCFA, is the first interagency effort addressed at progression in renal disease.

AIDS RESEARCH

Question. Dr. Gorden, can you tell us about what you're supporting in AIDS research?

Answer. The NIDDK supports and conducts research related to the acquired immunodeficiency syndrome (AIDS) relevant to the disease and special emphasis areas within the Institute's mission. Though AIDS is a relatively recent addition to the Institute's research program, the NIDDK is contributing to this effort both intramurally and extramurally. The NIDDK intramural program is engaged in promising efforts to develop anti-viral agents to fight AIDS. The NIDDK is particularly well positioned to do this by virtue of its world-premiere researchers in the field of structural biology. Using highly sophisticated x-ray techniques, these researchers can study the three-dimensional structure of both HIV and human immune system proteins. NIDDK researchers are evaluating three newly synthesized derivatives of the clinically effective HIV drug dideoxycytidine. In other studies, NIDDK scientists are attempting to produce better derivatives of the drug azidothymidine (AZT), and to develop highly targeted agents to inhibit the reverse transcriptase and protease enzyme activities that allow HIV to insert its genetic material into the DNA of the body's immune cells.

Extramurally, the Institute has implemented several initiatives to encourage AIDS research and has funded over 30 grants as a result of these initiatives. Many of the disease and emphasis areas within the mission of the Institute are directly relevant to AIDS, including gastroenterology and nutrition, endocrinology, end-stage renal disease, urology, and hematology. For example, the alimentary canal is one of the key routes of HIV infection and transmission. Another important area of research is to uncover the metabolic and endocrine basis of the AIDS wasting syndrome. Research on the urogenital tract--one of the major sources of HIV transmission--is vital to understanding the replication of the virus and the treatment and prevention of the disease. The incidence of HIV infection in the existing hemodialysis population is also a concern, as is renal disease resulting from HIV infection and leading to end-stage renal disease.

In one study of HIV-infected children, NIDDK-supported investigators determined, after examining over 150 children with AIDS, that those who acquire the disease in the womb sometimes develop renal complications, especially black children.
NIDDK grantees also recently investigated the nutritional status of over 50 adult AIDS patients. Because these patients consume fewer calories than healthy individuals, the research team found that nutrition may be a major predictor of an AIDS patient's survival. Moreover, these studies indicate that the rate of decrease in the complex protein albumin in the blood of these patients may define a function that limits their survival.

In another NIDDK-funded study, researchers found that HIV may directly infect megakaryocytes, bone marrow cells that manufacture mature blood platelets. Previous studies yielded no such evidence of direct HIV infection. Rather, the abnormalities seen in megakaryocytes were thought to be caused by other immune cells, such as lymphocytes and monocytes, which the AIDS virus had infected. This finding may help explain why some AIDS patients have a severely lowered level of blood platelets, a condition called thrombocytopenia, which results in abnormalities in blood clotting.

Continued application of existing expertise in these areas, and new investigations related to AIDS, could have a great impact on understanding the pathogenesis of the disease and its complications, as well as on the treatment of AIDS patients.

OBESITY RESEARCH

Question. Dr. Gorden, what research direction is your Institute taking to uncover the causes of obesity and its associated health risks?

Answer. The NIDDK supports approximately 150 research projects, for over $20 million, related to obesity. Major emphasis is in the areas of energy metabolism, control of food intake, fat cell biology, genetic and environmental factors, and therapeutic approaches to the treatment of obesity. The NIDDK is the primary NIH institute focused on obesity as a total disease entity and a national health problem. We are also the institute which has historically pursued basic research, both intramurally and extramurally, on nutrient metabolism and energy expenditure as a foundation for disease-oriented studies.

NIDDK scientists have made enormous progress in understanding the role of genetic and metabolic factors in obesity. For example, they have shown definitively that individuals with low metabolic rates are at greater risk for gaining weight than people with higher metabolic rates, and they have substantiated that obesity is a familial trait that may be genetically determined.

New and potentially important fat cell products have been identified. One such product is adipsin, an enzyme that is thought to be involved in the regulation of fat cell metabolism. Research on animal models also suggests that a regulatory interaction between the obesity gene and adipsin gene may be faulty. Understanding how fat cells differentiate and how they are regulated may lead to promising new avenues for the treatment of obesity.

The enzyme lipoprotein lipase may play a key role in obesity. This enzyme breaks down dietary fat into fatty acids and monoglycerides that may be used for energy or reconverted to fat that is stored in adipose tissue. One study suggests that increased lipoprotein lipase activity may at least partially predispose individuals to regain weight following weight reduction.

The NIDDK continues to support studies on obesity-related health risks. Recently, it has been found that moderate intensity physical conditioning can ameliorate non-insulin dependent (Type II) diabetes in obese individuals, which gives hope for potentially positive results in intervention programs. It has also been shown that total body weight is not independently related to either sex hormone levels or cardiovascular disease risk factors, whereas the individual body composition parameters--fat mass and lean mass--are significant determinants of both. These findings emphasize the importance of body composition rather than body weight or relative weight in determining energy expenditure and cardiovascular risk status in obese individuals. Lastly, we now know that fat concentrated in the abdominal area appears to pose a greater health risk than fat stored on the hips, although the risk factors for abdominal fat storage have not been clearly identified.

We know that obesity is strongly correlated with non-insulin dependent diabetes and are seeking to understand the basis for this correlation.

ERYTHROPOIETIN

Question. Dr. Gorden, the Food and Drug Administration has recently approved a drug that can help reduce anemia in patients suffering from kidney failure. Can you tell us about this drug and how NIDDK helped in its development?

Answer. Erythropoietin is a naturally occurring growth hormone, produced in the kidney, which causes a rise in the formation of red blood cells. The clinical importance of erythropoietin has been recognized for many years, since patients with severe kidney dysfunction have significantly reduced plasma erythropoietin levels, have chronic anemia as a result, and have been treated for the anemia with frequent blood transfusions.

The NIDDK has supported the study of erythropoietin for many years to determine its role in blood cell formation, and to clarify its formation in the kidney. Studies have been hampered by the limited amount of pure erythropoietin available. In 1987, NIDDK-supported investigators announced the isolation of the erythropoietin gene, and, in collaboration with a private company, which entered into the commercial production of pure recombinant human erythropoietin in vitro, began a trial of erythropoietin in patients with renal failure who were on dialysis. The trial, which was worldwide in scope, and to which the NIDDK contributed funds, found a rapid correction of the anemia by the erythropoietin leading to marked improvement in the quality of life for the patients studied. Very few adverse effects were found.

In 1989, the use of recombinant human erythropoietin was approved by the U.S. Food and Drug Administration and a wide use of this new drug is being made in patients with renal disease. Its use in patients with anemia from other causes and the possibility of other applications for its use are being investigated. This is a dramatic example of the application of biotechnology to human disease, which has led to a major improvement in the treatment of patients with debilitating diseases, such as AIDS.

ENDOCRINOLOGY

Question. Dr. Gorden, I think all the recent press interest in thyroid disease has focussed attention on the importance of the endocrine system. How are you developing your research program in this area?

Answer. Endocrinology is an exciting area in which acquisition of basic knowledge has progressed rapidly. Hormones and growth factors are major regulators of bone remodeling, and advances in endocrinology are leading to new understanding of osteoporosis. New techniques in immunology are being applied to autoimmune thyroid diseases such as Graves' disease, and are shedding new light on the pathogenesis of these disorders. Hormones long recognized to play major roles in the endocrine system may also serve as messengers in the immune and nervous systems and may integrate these systems with the endocrine system. Many endocrine disorders are due to benign tumors of pituitary, thyroid, parathyroid, adrenal and other endocrine glands. Recent work has identified some specific genetic changes which lead to formation of benign endocrine tumors; this work has great importance not only for the specific endocrine diseases involved, but for understanding of cancer and neoplasia. Rapid progress is also being made in elucidating the mechanisms by which hormones regulate gene expression and thus growth and development.

NIDDK seeks to complement its portfolio of individual endocrinology research projects with multidisciplinary research projects directed at the pathogenesis, diagnosis and treatment of endocrine disorders, as well as at fundamental endocrinology. To accomplish this, a Request For Applications for Programs of Excellence in Endocrinology was issued in 1989 with awards expected in 1990.

Thyroid disorders are extremely common, and NIDDK is supporting a component of the National Health and Nutrition Survey which will provide data on the prevalence of hyper- and hypothyroidism in the U.S. population. Another common endocrine disorder is hyperparathyroidism, and this disorder is being diagnosed with increasing frequency in asymptomatic patients who may be at risk for long term complications such as osteoporosis. NIDDK plans to convene a consensus conference in October 1990 to address issues related to the management and monitoring of such patients.

DIABETES RESEARCH

Question. Dr. Gorden, you have told us that one form of diabetes is caused when a person's immune system attacks the cells that produce insulin. What hope is there for curing this disease by turning down the immune system?

Answer. The explosion of basic knowledge about the immune system that has taken place in the last decade or two has provided opportunities for new treatments of all autoimmune diseases including insulin-dependent diabetes mellitus (IDDM). The most exciting potential for this line of research lies in the chance for "prevention" of the autoimmune destruction of the insulin producing beta cells of the pancreas that causes IDDM in those who are otherwise destined for this disease. In addition, the potential success of a "cure" for IDDM by the transplantation of beta cells into those patients whose own have already been destroyed will be enhanced by new therapies designed to prevent immune rejection.

In several animal models of IDDM, a number of immunomodulatory drugs and treatments have proven to be successful in preventing the onset of diabetes. Unfortunately, all of the immune interventions presently available have side effects that must be carefully evaluated and weighed against the benefit. Over the next five to ten years, I would anticipate that we will see continued aggressive pursuit of this whole area of research in further experimental animal studies using many different treatments as well as the initiation of human clinical trials involving those beneficial and safe therapies identified from the animal studies. This area is a prime example of the power that the synergistic process of basic research, experimental animal studies and human clinical trials can provide toward the alleviation of disease.

KIDNEY DISEASE CLINICAL TRIAL

Question. Dr. Gorden, I am interested in the diet therapy study--the clinical trial on Modification of Diet in Renal Disease or MDRD. Can you bring us up to date on this trial and its fiscal impact on the Institute?

Answer. The Modification of Diet in Renal Disease (MDRD) Study is a multicenter clinical trial studying the effects of diet and blood pressure on kidney disease. The primary objective of the study is to determine whether low and moderate protein and phosphorous diets and careful control of blood pressure among persons with chronic kidney disease can significantly slow down loss of kidney function, thereby reducing or eliminating the need for hemodialysis or transplantation. This investigation, supported by the National Institute of Diabetes and Digestive and Kidney Diseases in conjunction with the Health Care Financing Administration, is currently midway through the recruitment period. Fifteen medical centers located throughout the United States are collaborating in this trial and are actively seeking volunteers to participate in the study.

Progress in the study to date has been encouraging. For the first time in a major clinical trial, a highly accurate technique for measurement of kidney function (measurement of glomerular filtration rate) has been successfully utilized. Study physicians are now better able to determine the levels of residual kidney function in patients and assess the effect of the study intervention on disease progression. Nationwide, nearly 1,000 persons have been screened thus far to determine eligibility for the study and 200 have been entered into the study. A major mass media campaign now is being conducted by the participating medical centers to further publicize the study and complete recruitment. Finally, a number of unique educational materials have been developed by MDRD dietitians to assist study participants in tracking nutrients (protein, sodium, calories, phosphorous) in foods purchased at grocery stores or eaten in fast food restaurants.

Recruitment will continue through the end of September 1990 and study participants will be followed up until December 1992. It is anticipated that results from the study will be available in the summer of 1993.

The fiscal impact of the MDRD in 1989 was substantial, and the Institute was able to award about 30 fewer regular research grants than we would have if we had not had the trial. In 1990, the cost of this study is approximately $6.9 million, and in 1991 and 1992, this will increase to $10 million per year.

PEPTIC ULCERS

Question. Dr. Gorden, tell us about the theory that bacteria may cause peptic ulcers. Has any treatment been devised to combat these infections?

Answer. Since the early eighties researchers have been reporting the frequent presence of a spiral organism on the mucous membrane of the gut in patients with gastritis or peptic ulcer disease. Subsequent research has led to the conclusion that the organism, previously called Campylobacter pylori and now identified as Helicobacter pylori, is important in the origin and development of peptic ulcer and gastritis. That conclusion has enormous diagnostic and therapeutic implications because approximately 75 to 80 percent of gastric ulcers are associated with H. pylori infection. Peptic ulcer disease results from an imbalance between the secretion of acid by the stomach and the ability of an area of the mucosa to resist that digestive activity. From gastric mappings, NIDDK grantees have recently demonstrated that the bacterium causes a progressive inflammation from the cavity to the body of the stomach. This inflammation ultimately leads to a pattern of gastritis. The damaged cells are then susceptible to acid and peptic digestion, which can result in gastric ulcers, while the infected tissue in the intestine can lead to the formation of duodenal ulcers. These investigators have gone on to devise methods for detecting the bacterium, which include direct staining, a urea breath test, and an immunoassay for the presence of antibodies. What is most important is that they have shown that an ulcer can be healed and its recurrence prevented by eradicating the bacterial organism with combined bismuth and antibiotic therapy. Ultimately, if confirmed through additional clinical studies, these findings may lead to wide scale control of peptic ulcer disease, a condition that affects 10 percent of the American population.

GALLSTONES

Question. Dr. Gorden, there are several treatments to treat gallstones without surgery. Which of these is most effective?

Answer. First, I would like to make the point that patients with asymptomatic gallstones are unlikely to develop major symptoms or complications, and therefore, should not receive either surgical or nonsurgical therapy except under unusual circumstances. At present, surgical excision of the gallbladder is a gold standard for the treatment of symptomatic gallstones to which any alternative therapy must be compared. For patients with biliary symptoms who prefer a nonsurgical approach, medical therapies are available for specific indications. Those with small stones will be best treated by oral bile acid dissolution alone. Others with large or multiple stones with little or no calcification may be excellent candidates for rapid dissolution of their stones using methyl tert-butyl ether. This therapy requires invasive radiologic methods to catheterize the gallbladder and directly instill the ether, but may be lifesaving in patients who are poor candidates for general anesthesia or surgery. Methyl tert-butyl ether is still investigational in the United States, but evidence suggests that it can be an effective and safe therapy for selected patients, and may be used for rapid dissolution of large fragments after lithotripsy. Biliary lithotripsy is a new technology that is minimally invasive and can be very effective and safe in a highly selected group of patients, which may comprise less than 15 percent of patients with gallstones. Lithotriptors fragment gallstones using shock waves generated under the water, which are then transmitted to the stones through a water bath or water-filled cushion. Initial studies have shown that optimal results are achieved with only those patients who have solitary stones of less than 20 millimeters in diameter. Lithotriptor devices have not yet received Food and Drug Administration approval. If they are approved in the future, their clinical impact will depend on how often the therapy effectively relieves biliary symptoms and complications and how its costs compare with those of alternative therapies. Because of the risk of stone recurrence and the efficacy and safety of elective removal of the gallbladder, surgery should be the first choice for most patients who are young and healthy.

CYSTIC FIBROSIS GENE

Question. Dr. Gorden, I was delighted to hear about the discovery of the cystic fibrosis gene. How do you plan to follow up on this achievement and maintain the research momentum in this field?

Answer. Early this year we will be publishing a Request for Applications (RFA) entitled "Research on the Molecular Basis of Cystic Fibrosis." This will be a unique announcement, jointly sponsored by the NIDDK and the Cystic Fibrosis Foundation, each of which hopes to fund about 10 new research projects. Since the CF gene product appears to be involved in the control of ion transport across cell membranes, this will be a major area we will want to study. The kind of projects we hope to attract with this RFA will look at just how the product of the CF gene works, in normal and in CF cells; how other components of cell membranes are involved; and the control mechanisms for ion transport pathways, which are defective in CF patients. We hope that this knowledge will lead to methods for bypassing the defective control system in CF cells, to drugs to alter the mutant CF gene product, or to gene therapy to replace the erroneous protein with the correct version.

In addition to this RFA, I am pleased to report that our Advisory Council has just approved the funding for a major new program project grant to an NIDDK-supported researcher who was one of the discoverers of the CF gene. This program project includes several gene therapy subprojects, one directly related to CF, and others that are aimed at gene therapy techniques and at different metabolic diseases.

KIDNEY DISEASE OF DIABETES

Question. Dr. Gorden, as you know, this Committee is very concerned about kidney disease of diabetes. Can you tell us about what you are doing to address this major health problem?

Answer. The kidney disease of diabetes mellitus (KDDM) is the leading cause of end-stage renal disease in the United States. The

NIDDK has established a multifaceted effort to conduct basic and clinical studies on KDDM, including efforts to study the epidemiology and natural history of KDDM in non-insulin dependent diabetes. In 1989, we supported over 40 research grants, contracts, and intramural research projects in the area of KDDM for $9.6 million. Our KDDM program has expanded nearly five-fold since 1986.

The NIDDK has taken steps to address the many unanswered questions surrounding KDDM. The Institute issued two Requests for Applications--one each in 1987 and 1988--to enhance research in this area. Many projects subsequently were funded, including nine new grants in FY 1990. In January of this year, the Institute initiated a new RFA in response to Congressional interest to increase emphasis in KDDM. Of course, grants awarded through this process will be based on the scientific quality of the applications received.

The Institute's KDDM effort includes several other major ongoing activities. The NIDDK's Division of Kidney, Urologic and Hematologic Diseases and Division of Diabetes, Endocrinology, and Metabolic Diseases are collaborating on this initiative. One component of our KDDM efforts is to investigate the rate of development and severity of KDDM in two groups of insulin-dependent diabetes mellitus patients who are being studied in the Diabetes Control and Complications Trial (DCCT), which is attempting to determine whether strict control of blood glucose levels can ameliorate the complications of diabetes. A Comprehensive Study of the Natural History of KDDM in the Pima Indian population was initiated involving NIDDK intramural and extramural collaboration. The Institute has also established new clinical trials on the potential therapeutic effect of blood-pressure lowering drugs in delaying the progressive loss of renal function due to KDDM. These clinical intervention studies are being conducted by The Johns Hopkins University and by Rush Presbyterian-St. Lukes Hospital. In addition, in 1986 and 1989 the Institute sponsored international symposia on KDDM, during which the "state of the science" was discussed and recommendations were developed.

The underlying mechanisms that cause KDDM are unknown. Therefore, its prevention and treatment require intensive investigation at all levels of research--basic, clinical, and epidemiologic.

GENETICS OF DIABETES

Question. Dr. Gorden, currently genetics research is a very promising area. What are the prospects for finding the gene or genes that cause diabetes?

Answer. The recent discovery of the CF gene rightly has been called a triumph for modern molecular biology, and is an impetus for intensifying the search for defective genes in other diseases, such as diabetes. A wide array of research studies points to the importance of genetic factors in diabetes and provides a strong rationale for pursuing this type of research.

The discovery of specific genes related to diabetes poses a greater challenge than the CF effort because diabetes is actually several distinct diseases. It would also appear that each form of diabetes arises in the context of a unique combination of multiple gene defects rather than a single gene defect.

It is well established that insulin-dependent diabetes (IDDM) is associated with genes in a specific area of the genome called the HLA locus. There is evidence that in some populations, a specific single letter of the genetic code in this locus is highly correlated with diabetes susceptibility. Studies in animal models of IDDM have suggested that several other genes may be involved with this disease as well. Non-insulin dependent diabetes (NIDDM) shows a strong hereditary pattern which indicates the existence of a significant genetic component to this form of diabetes as well. We are less certain of the basic underlying causes of NIDDM which likely include the interaction of defects in several metabolic processes. Therefore, the specific identification of genes for this disease may require complex and sophisticated analyses that will push the frontiers of our technology.

Recently, the Institute has taken specific action to stimulate research in the areas of genetics, molecular biology and immunology. The process began with colloquia designed to bring together basic scientists with diabetes researchers. The Institute now has begun to receive interdisciplinary research proposals as a result of these colloquia. Workshops and conferences have also been held to highlight and characterize racial/ethnic groups with high rates of diabetes (i.e., Blacks, Hispanics and Native Americans) that may be important populations in which to look for relevant genes.

NUTRITION GUIDELINES

Question. Dr. Gorden, the press has reported the recent publication of the Tenth Edition of the Recommended Dietary Allowances. Can you tell us how the new edition will aid nutrition research and describe the role your Institute played in this effort?

Answer. The Recommended Dietary Allowances (RDAs) are a principal guide for developing nutrition programs and policies and are periodically adjusted to reflect the increasing scientific understanding of human nutrition. For nearly half a century, at the Federal government's request, the National Research Council of the National Academy of Sciences has conducted periodic reviews of the essential vitamins and minerals in the diet. The first RDAs were published in 1941 as a guide for meeting the dietary needs of U.S. troops during World War II. Since then, their use has been expanded by various groups to help provide nutritional guidance for healthy persons. For example, the U.S. Department of Agriculture uses the RDAs to evaluate the adequacy of the U.S. food supply, to establish standards for food assistance programs, and to determine the nutritional status of the U.S. population. The Food and Drug Administration used the seventh edition of the RDAs to derive its U.S. Recommended Daily Allowances, which help set standards that guide how the nutritional content of foods is listed on product labels. Another use of these guidelines is to aid in the development of new food products. From a research point of view, when conducting nutrition studies, the RDAs provide a reference or standard against which adequate nutrient intake or nutrient deficiencies can be measured. The National Institute of Diabetes and Digestive and Kidney Diseases has supported the development of the Recommended Dietary Allowances for more than 25 years. The effort to produce the tenth edition was supported under contract by the NIDDK.

INTERSTITIAL CYSTITIS

Question: Why were only two interstitial cystitis (CF) projects approved under the RFA issued specifically for that purpose and for which you had designated $800,000?

Answer: In FY 1989, the NIDDK funded two research grants as a result of its research solicitation on interstitial cystitis (CF) entitled "Request for Applications (RFA) on the Role of Inflammatory Mediators in the Initiation and Maintenance of Chronic Interstitial Cystitis of the Urinary Bladder." We think it is important to look at this RFA in the context of the current NIDDK portfolio of research on IC, which totaled approximately $1.8 million in FY 1989 for 10 regular research grants and one pilot data base. This portfolio represents an impressive growth rate achieved over a very short period of time. In FY 1986, there was virtually no research at all being conducted on IC.

With respect to funding in FY 1989, the NIDDK expended approximately $600 thousand in new funds on IC. The Institute funded two grants from the RFA, as well as one grant through the regular grant application process, and one grant to an existing George O'Brien Kidney and Urologic Diseases Research Center to establish a pilot data base on IC. This represented about a 50 percent increase over the FY 1988 funding level for IC.

Regarding your specific question about the RFA, the NIDDK received 15 research grant applications in response to this research solicitation. The special group of non-governmental scientific experts convened to review and evaluate these applications assigned them numerical scores, based on scientific merit and technical feasibility, that ranged from a low of 163 (the best score) to a high of 473 (the worst score). One application was disapproved.

In the RFA, the NIDDK indicated its intent to expend up to $850 thousand on scientifically meritorious grants resulting from the solicitation. However, given the scientific-merit scores assigned to the resulting applications, the NIDDK was able to fund only two grants from this RFA. The quality of the other applications did not place them within the Institute's fundable range.

We have tried to underscore to the research community that dollar amounts published in RFAs are "targets" and not absolute funding "set-asides." The driving force behind NIH and NIDDK funding decisions remains the scientific merit of the research grant applications, because our common goal must be to build a high-quality and productive research program on IC.

Question: Do you have plans for any further RFAs?

Answer: To date, the NIDDK has published three RFAs on IC: two for biomedical research grant applications and one for a pilot IC data base. In addition, the NIDDK has sponsored conferences and workshops to encourage investigators to pursue this field, and has published a "Program Announcement," a general type of research solicitation, with the same objective. Encouraging research on IC is a high priority of the NIDDK, which welcomes research grant applications in this area. During 1989, the Institute's Kidney, Urologic and Hematologic Diseases published Requests for Applications in only two disease areas, and one of these was IC. The Institute will continue to publish Program Announcements on IC each fiscal year, and will publish RFAs periodically, to pursue emerging research leads suggested by ongoing studies, as well as by conferences and workshops. The Institute submitted a five-year plan for research efforts on IC to the Appropriations Committees in 1989.

Question: When do you plan to issue an RFP for the IC National Registry?

Answer: The NIDDK has carefully considered the possibility of establishing a national registry on IC, as requested by the Congress. The Institute has concluded, however, that it would be most appropriate to test the usefulness of the newly developed diagnostic criteria before pursuing the concept of a national IC registry. In its five-year plan for IC, submitted to the Congress in April 1989, the Institute outlined the advantages of establishing a pilot IC data base, rather than a national registry, at this point in time. The most important consideration is that IC remains a disease with widely varying symptoms. Thus, for research purposes, it is important to begin to collect data in a "pilot" mode on a well-defined group of patients who share similar characteristics, based on the preliminary set of diagnostic criteria which the NIDDK has developed in conjunction with the IC research and IC voluntary health communities. Such a pilot data base offers the most promising opportunities for finding clues about the causes of IC in these patients, and it also provides a well-defined group of patients for possible future clinical studies and trials. In contrast, given the current state of knowledge about IC, the NIDDK believes that it would be scientifically premature to set up a national registry for IC patients, for whom clinical data could be expected to be extremely variable. In FY 1989, the Institute made a grant award to an existing George O'Brien Kidney and Urologic Diseases Research Center to establish a pilot IC data base.

NEGOTIATED REDUCTIONS

Question. Dr. Gorden, I understand that the cost of biomedical research outpaces the inflation rate by approximately 2 percent. How do you account for this dynamic? Given the fact the Institute's budget rises only 4% over 1990, what impact will this have on the Institute's activities in fiscal year 1991?

Answer. In order to maintain approximately the same total number of research project grants and centers we have had to negotiate reductions from the Study Section approved funding levels for each grant and center.

Question. What will the Institute's downward negotiation rate on research project grants and center grants be in FY'91? How does this compare to fiscal years 89 and 90?

Answer. For research project grants, we will be making cuts of 11% in 1991. This compares to cuts of 11% in 1989 and 12% in 1990. Centers will be cut 30% in 1991 compared to 21% in 1989 and 25% in 1990.

RARE METABOLIC DISEASES

Question. Dr. Gorden, I understand that many children within Amish and Mennonite communities are afflicted with rare metabolic diseases, such as glutaric aciduria. I further understand that many of these disorders may be treatable through early detection and changes in diet. To what extent is the Institute aware of these problems and the potential treatments? Has the Institute approved any grants in this area research? If so, were there sufficient funds to support the grant or grants?

Answer. This Institute is well aware of the rare genetic metabolic diseases such as glutaric aciduria which afflicted the Amish and Mennonite communities. The two distinct types of glutaric acidurias are complex and heterogeneous diseases. There are very early onset forms which result in death during the neonatal period, as well as later onset cases which may also cause sudden death. A connection between glutaric aciduria and sudden infant death syndrome is presently being investigated. One variant of the disease responds to dietary supplementation by riboflavin, which is a component of the vitamin B complex. The NIDDK supports three research programs which explore the diagnosis, molecular biology, pathophysiology and treatment of the disease. This support amounted to a total of $550,903 during FY 1989.

NIDDK also supports research in another rare genetic metabolic disease which afflicts the Amish and Mennonite communities, namely, Maple Syrup Urine Disease (MSUD). This disease, which is due to an enzymatic defect and is also heterogeneous, develops during early childhood and causes mental retardation and ultimately death. Dietary intervention, by control of the protein intake especially the amino acids valine and leucine, is an accepted therapeutic approach for this disease. The NIDDK supports five research projects which explore the diagnosis, the molecular and genetic basis and therapeutic approaches to MSUD and totaled $921,716 during FY 1989. The NIDDK, in collaboration with the NICHD, has recently issued a Request for Applications on "Nutritional Therapy for Inborn Efforts of Metabolism.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

STATEMENT OF DR. DUANE ALEXANDER, DIRECTOR

SUMMARY STATEMENT

Senator **HARKIN**. Now we will go to Dr. Alexander, and the National Institute of Child Health and Human Development.

Dr. Alexander, your budget request is $461.47 million for a 4.19-percent increase.

Welcome and please proceed.

PROGRAM PRIORITIES

Dr. **ALEXANDER**. Thank you, Mr. Chairman. The research program of the NICHD cuts across age and disease categories and encompasses the study of normal as well as abnormal development. The broad mission of our Institute and the relevance of that mission to some of the most critical public health problems of our time are reflected in the fact that NICHD research addresses 8 of the 10 Public Health Service priorities recently identified by the Assistant Secretary for Health.

These eight priorities include infant mortality, AIDS, strengthening the family, drug and alcohol abuse, improving minority health, enhancing health promotion and disease prevention, environmental and occupational health, and maintaining research capacity.

Senator **HARKIN**. Excuse me, does drug and alcohol abuse encompass tobacco abuse?

Dr. **ALEXANDER**. Yes; it does, sir.

Senator **HARKIN**. Continue on, but I want to ask you more about what you are doing on that.

INFANT MORTALITY

Dr. **ALEXANDER**. I would be glad to tell you that. Reducing infant mortality is a long-standing national priority. The 1988 rate reached 9.9 deaths per 1,000 live births, the lowest level ever recorded and a substantial reduction from our 1978 rate of 13.8, though still short of the 1990 objective of 9 deaths per 1,000.

Current data indicate that birth defects, sudden infant death syndrome and low-birth weight are the leading causes of death in infants. To reduce this Nation's infant mortality rate, NICHD is placing greater emphasis on research to elucidate their causes.

AIDS RESEARCH

AIDS is an increasing problem among infants, children, and women, and will soon become the fifth leading cause of death for children and young people from birth to 24 years of age. The NICHD's AIDS research program focuses on preventing transmission of the virus, treating the infection in infants and children, and understanding the biological activity of the virus. The NICHD and NIAID are combining their pediatric AIDS clinical trials networks as Dr. Fauci indicated earlier, thereby ensuring that the vast majority of HIV infected children and pregnant women will have access to clinical trials and to state-of-the-art research and care.

CONTRACEPTIVE DEVELOPMENT

The NICHD research program in contraceptive development addresses the problem of unintended pregnancy. The availability of safe, effective, and acceptable methods of contraception is essential so that couples can better regulate their fertility. Other NICHD research is directed at helping couples to have babies by providing new approaches for overcoming infertility or reproductive diseases or disorders.

CHILD DAY CARE

More than 5 million children under the age of 3 are now placed in some form of day care while their parents work. To address the many questions concerning the consequences of day care, the NICHD has launched a major cooperative clinical study of the emotional, social, and intellectual development of children in varying child care settings.

FAMILIES WITH HANDICAPPED CHILDREN

Other families are faced with the additional challenge of caring for a child with a physical handicap or mental retardation. The Institute has initiated a special research program focused on the families of handicapped children, the way they function and the effects of family environment on the children.

PREPARED STATEMENT

Many of the problems I have mentioned, particularly infant mortality and teen pregnancy, affect minorities disproportionately. All of the research programs of the NICHD have the potential for improving minority health and some are targeted specifically to minorities.

Mr. Chairman, our 1991 budget request favors basic research and totals $461,473,000.

I will be pleased to answer any of your questions.

[The statement follows:]

STATEMENT OF DR. DUANE FREDERICK ALEXANDER

The research program of the National Institute of Child Health and Human Development (NICHD) cuts across age and disease categories and encompasses the study of normal, as well as abnormal, development. The broad mission of the Institute and the relevance of its mission to some of the most critical public health problems of our time are reflected in the fact that NICHD research addresses eight of the ten 1992 Public Health Service priorities recently identified by the Assistant Secretary for Health, Dr. James Mason.

These eight priorities include infant mortality, AIDS, strengthening the family, drug and alcohol abuse, improving minority health, enhancing health promotion and disease prevention, environmental and occupational health, and maintaining research capacity.

Reducing the infant mortality rate is a long-standing national priority. Not only is it one of the priority areas for 1992 identified by the Public Health Service, but reducing infant mortality was one of the primary health objectives for the nation established in 1980 in the Surgeon General's report Promoting Health/Preventing Disease.

The goal set for infant mortality in 1990 in that report was 9 deaths per 1,000 live births. The 1988 rate reached 9.9, the lowest level ever recorded and a substantial reduction from the 1978 rate of 13.8, but still short of the 1990 objective.

One objective that was met is a reduction in infant deaths in the area most amenable to technological intervention--neonatal mortality, defined as deaths occurring up to 28 days of age. Many of the technological advances that enabled a drop in this rate from 9.5 to 6.7 are attributable to NICHD research that has led to improvements in preventing birth trauma, providing nutrition, and treating gastrointestinal diseases, hypoxia, and respiratory distress syndrome.

However, other areas have shown little improvement over the past 10 years: there is still a broad gap between infant mortality rates for blacks and whites; there has been virtually no increase in the proportion of women receiving prenatal care early in pregnancy; there has been no reduction in the incidence of low birth weight and an increase in very low birth weight among blacks, a major factor in infant mortality; the proportion of babies born to unmarried women has increased; and AIDS--an infection not even identified 10 years ago--has emerged as a leading cause of death among infants and children.

The NICHD and the scientific community have worked hard over the past decade to achieve what progress has been made but it is obvious that the task is far from done. The Institute remains committed to the belief that research can help to overcome these and other problems. We enter a new decade armed with renewed determination and scientific advances to ensure that the PHS priorities for 1992 are addressed and the health goals set for the nation for the year 2000 are realized.

Current data indicate that birth defects are the leading cause of death in infants. To reduce this nation's infant mortality rate, a greater emphasis must be placed on research to elucidate the causes of these developmental defects. New technology allows investigations of developmental processes that never before have been explored. For example, several human birth defects now can be studied in animal models. NICHD has developed two mouse models for neural tube defects, one of the most common developmental defects of the central nervous system. Other scientists are testing a vaccine for cytomegalovirus, the leading cause in this country of congenital infections that damage infants, and studying the genes involved in hereditary immunodeficiency diseases.

An immunodeficiency disease that is acquired--AIDS--is an increasing problem among infants, children and women. Experts predict that during the 1990s AIDS will become the fifth leading cause of death for children and young people from birth to 24 years of age. The NICHD AIDS research program focuses on preventing the transmission of the virus, treating the infection in infants and children, and understanding the biological activity of the virus. A major laboratory study was completed recently to evaluate the suitability of using condoms, and condoms plus spermicides, in preventing the transmission of HIV. The results of this study show that the condoms on the American market are of high quality and should provide a substantial degree of protection from HIV and other sexually transmitted diseases in the general population. This and other studies have also demonstrated that spermicides used with condoms offer additional protection.

In ongoing research to develop better treatments for HIV infected infants and children, the NICHD is investigating the role of intravenous immunoglobulin in preventing bacterial infection in HIV positive children. The trial is being conducted in 30 hospitals around the country and has enrolled more than 330 children. This NICHD pediatric AIDS clinical trials network is joining forces with the pediatric AIDS network supported by the National Institute of Allergy and Infectious Diseases. By the union of the two networks, the vast majority of HIV-infected children and pregnant women will have access to clinical trials and to state-of-the-art research and care.

While AIDS is the newest and one of the most devastating diseases affecting family life in America today, other erosions are at work as well. More unmarried women, many of them teenagers, are becoming mothers each year. Most of these pregnancies are unplanned and the young mothers are ill-equipped to deal with the demands of raising children. The adverse consequences of this premature childbearing are felt through subsequent generations. The NICHD research program in contraceptive development addresses the problem of unintended pregnancy. The availability of safe, effective and acceptable methods of contraception is essential so that couples can better regulate their fertility. NICHD-supported scientists are completing phase II clinical study of a polyvinyl sponge containing a spermicide. The study has shown that, overall, the sponge is as effective as the cervical cap or diaphragm, and is an attractive alternative to the consumer because of the ease of its use.

Clinical trials of two chemical analogs of a hormone produced in the brain that regulates reproductive processes are under way to ascertain the potential of these drugs for fertility regulation in men. If successful, these drugs could result in the first non-barrier, reversible contraceptive for men.

Other research is directed at helping couples to have babies. The NICHD supports a broad basic science program to provide new approaches for overcoming infertility or reproductive diseases or disorders. Scientists in one such study have discovered that nearly half of women with unexplained infertility produce antibodies to their partner's sperm. Finding this possible immunologic cause of infertility is the first step to restoring fertility to these women.

Even families with planned, wanted children have challenges to face. The "traditional" family with a father, who earns the family income and the mother who is a full-time homemaker, is far less prevalent than it used to be. More than five million children under the age of three are now placed in some form of day care while their parents work. To address the many questions concerning the consequences of day care, the NICHD has launched a major cooperative clinical study of the emotional, social, and intellectual development of children who have had varying child care experiences.

Other families are faced with the additional challenge of caring for a child with a physical handicap or mental retardation. The NICHD has initiated a special research program focused on the families of handicapped children, the way they function, and the effects of family environment on the children.

Some children, no matter how loving or responsible their parents, succumb to the temptations available in modern society. The NICHD conducts and supports research to expand our understanding of why some children, particularly adolescents, engage in risk-taking behavior leading to drug or alcohol abuse or to sexual behavior. Because women who abuse drugs often give birth to addicted infants, there is a particular need to support research on the effects of these drugs on fetal development. Compounding the problem is the fact that many IV drug abusing women who become pregnant have infants with HIV infection.

The NICHD supports research to understand these risk-taking behaviors so strategies to prevent their occurrence can be designed. In one such study, investigators found that teenagers given a sexuality education program were no more or no less likely than adolescents not participating in the program to engage in sexual behavior. However, among those teenagers who were sexually active, those who had participated in the sexuality education program were much more likely to use contraception.

Many of these problems, ranging from infant mortality to teen pregnancy, affect minorities disproportionately. All of the research programs of the NICHD have the potential for improving minority health and some are targeted specifically to minorities. For example, in Baltimore, Maryland, an NICHD-supported project will utilize an intensive outreach program to bring women at high risk of poor pregnancy outcome into a comprehensive prenatal care system. By determining what approaches and which specific interventions work in this program, these can then be generalized to a larger population.

Underlying all of the research I have discussed today is a broad science base. The NICHD helps to maintain the Nation's research capacity through the support and conduct of research and research training. This year, an NICHD intramural scientist who first came to the Institute under a fellowship training program was awarded the prestigious Young Investigator Award by the Neuroscience Society for his work on glutamate receptors. Glutamate, a nerve signalling amino acid, probably holds the key to how the brain is damaged when deprived of oxygen and plays a role in fetal brain development and memory and thus in mental retardation. This award exemplifies the best at the NICHD and at the NIH--solid science combined with the development of new investigators. This is a tradition that we plan to maintain in the coming years.

Mr. Chairman, the National Institute of Child Health and Human Development FY 1991 budget request is $461,473,000. I would be pleased to answer any questions you have.

BIOGRAPHY OF DR. DUANE FREDERICK ALEXANDER

BIRTH	August 11, 1940, Baltimore, Maryland
MARITAL STATUS	Married Marianne Ellis, Washington D.C., June 23, 1963; two children
EDUCATION	Pennsylvania State University, University Park, Pennsylvania, B.S. Degree, Pre-Medical, 1962 Johns Hopkins University School of Medicine, Baltimore, Maryland, M.D. Degree, 1966
INTERNSHIP	Intern and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1966-1967
RESIDENCY	Assistant Resident and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1967-1968
MILITARY SERVICE	1968-1970: Surgeon (LCDR), U.S. Public Health Service, and Clinical Associate, Children's Diagnostic and Study Branch, National Institute of Child Health and Human Development, (NICHD) National Institutes of Health (NIH) Bethesda, Maryland

	1971-Present: From Surgeon to Medical Director, U.S. Public Health Service
FELLOWSHIP	Fellow in Pediatrics (Developmental Disabilities), John F. Kennedy Institute for Habilitation of the Mentally and Physically Handicapped Child, Johns Hopkins Hospital, 1970-71
LICENSURE	Maryland Board of Medical Examiners
CERTIFICATION	Diplomate, American Board of Pediatrics, 1973
POSITIONS HELD	
1971-74	Assistant to the Scientific Director, NICHD, NIH, Bethesda, Maryland
1974-78	Medical Officer (Staff), National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW
1978-82	Assistant to the Director, NICHD, NIH
1982-86	Deputy Director, NICHD, NIH
1986-present	Director, NICHD, NIH

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

CHILD HEALTH RESEARCH CENTERS

Question. Last year the Committee added $2 million and requested the initiative of child health research centers. What is the status of efforts to establish these centers?

Answer. The NICHD has developed guidelines for establishing and operating a program of child health research centers. These centers are intended not only to provide support for essential pediatric research but to enhance the ability of pediatric investigators to compete for other sources of funding. To announce the availability of funds for this program, the Institute issued a request for applications (RFA) on January 5, 1990. Over 130 copies of the RFA have been distributed in response to inquiries, and at least 25 strong applications are anticipated. The deadline for receipt of applications is April 23, 1990, with review scheduled to begin in July. It is expected that six centers will be funded in FY 1990.

DAY CARE

Question. Last year the Committee requested the Institute to conduct research on day care. Particularly the developmental, psychological, and health effects of leaving young children, infant to 3 year olds, in day care situations. I understand that six cooperative research efforts have been funded and that four more will be funded in fiscal year 1991. What can you tell us about research findings to date with regard to the most effective day care settings and environments?

Answer. The NICHD is currently supporting a network of ten research sites located across the country that is now undertaking a collaborative, prospective, longitudinal study of the psychological development of children of employed mothers. This study of 1,200 infants is designed to provide information about the effects of various patterns of early child care on the course of children's socio-emotional and cognitive development over the first three years of life. The study will show how these effects vary as a function of a list of variables, such as characteristics of the child, family and alternate care. The study will also identify the major factors influencing families' utilization of various alternate infant care arrangements. The planned study will take five years to complete. The earliest preliminary data will be available in approximately two and one-half years.

SIDS

Question. Dr. Alexander, the Committee has urged your Institute to complete the 5-year Sudden Infant Death Syndrome research plan. This year, fiscal year 1990, was the first year and I understand that this has not been fully implemented. For fiscal year 1991, you have requested $5 million. This amount is approximately $6 million short of the amount needed to fully fund the second year of the plan. Please tell the Committee what elements of the first year's effort have not been funded and what will be dropped from the second year's effort because of the funding shortfall reflected by your budget request.

Answer. The SIDS five-year plan was formally established in FY 1989 for implementation beginning in FY 1990. During the first year of the plan (FY 1990), we are issuing a request for contract proposals to support a tissue bank for specimens from victims of SIDS, developmental disorders, and other infant deaths. However, this activity will be reduced in scope from that outlined in the five-year plan in that the extent of tissues and registry information collected will be reduced, and medical examiner training and services needed for uniform nationwide collection of tissue will not be supported.

The pilot clinical trial of home apnea monitoring will not be initiated as proposed for the first year of the plan, because the research grant proposals have not been of sufficient scientific merit. Further, new scientific considerations obtained from expert consultants suggest that it would be more advantageous initially to solicit proposals for studies of life-threatening events detected at home by apnea monitors in high risk infants. This is planned for FY 1991. This information will allow us to design a better study of home apnea monitoring for implementation later.

In addition, we have not funded the interagency studies of SIDS risk factors. An epidemiologic and pathology study of SIDS risk factors in a selected Native American population has been planned but is not included in the President's budget request.

The following elements from the second year (FY 1991) also will be postponed: (1) development of and research on animal models of SIDS, (2) studies on the role of the immune system and infections in SIDS, and (3) a companion clinical study to the planned apnea monitoring study, which will examine relevant physiologic and behavioral parameters which may serve as prognostic clinical tests to identify infants at risk for SIDS.

AUTISM RESEARCH

Question. In 1989 the movie "Rain Man" provided many in the public with their first exposure to the severe developmental disability known as autism. As that movie recedes from public attention, I am concerned that NIH not recede from appropriate efforts to combat this condition. Please describe for the record the Institute's FY 1991 plans for encouraging, funding, conducting, and collating research on the causes and treatment of autism. Please also outline the Institute's preliminary thoughts on autism research efforts for future years so that the Committee can appreciate how proposed FY 1991 expenditures for this purpose relate to longer term efforts to understand and combat this condition.

Answer. The National Institute of Child Health and Human Development (NICHD) supports a variety of research on the developmental disabilities, including autism, with focus on studies of biological, behavioral and biobehavioral factors implicated in the causes of this condition. Several medical and behavioral studies are examining the effectiveness of pharmacological treatment on destructive behaviors exhibited by persons with autism.

In September 1989, the NICHD sponsored a consensus development conference entitled "Treatment of Destructive Behavior in Persons with Developmental Disabilities." The consensus development panel recommended a number of topics for future research, including understanding the biological causes of autism, which requires an increased effort in the fields of genetics, neurology, and physiology.

Research is also needed on the cause, form, severity, duration, and management of the self-destructive behaviors associated with autism. In addition, comparison of treatments, their components, and combinations of treatments are needed. The NICHD plans to encourage investigators to develop a multicenter network where studies would focus on the occurrence, contributing factors, and treatment of autism.

FUNDING OF RESEARCH PROJECT GRANTS (RPGs)

Question. The NICHD will support an estimated total of 1,431 competing and noncompeting RPGs in FY 1991, a decrease of one from the number in FY 1990, and with downward negotiation rates that are among the highest at NIH. But the NICHD award rate improves in FY 1991 to 22.5% from 19.8% in FY 1990. How do you explain this?

Answer. The award rate is the percentage of approved competing research project grant (RPG) applications that are funded in a fiscal year. Estimates of NICHD award rates for FY 1990 and FY 1991 are:

	Number of Approved RPG Applications	Number of Competing RPGs Funded	Award Rate
FY 1990 estimate	1,637	323	19.8%
FY 1991 estimate	1,611	362	22.5%

The 362 RPGs estimated in FY 1991 represent an increase of 39 grants over the FY 1990 level. This increase in competing RPGs is offset by a corresponding decrease of 40 noncompeting RPGs in FY 1991. As a result of this offset, the total number of RPGs, competing and noncompeting, is one less in FY 1991 than in FY 1990.

LEARNING DISABILITIES

Question. The Committee added $750,000 to the FY 1990 NICHD appropriation to fund an additional Learning Disabilities Center, for a total of three centers in this program. Has this new center been funded?

Answer. The request for applications (RFA) for the third Learning Disabilities Center was issued in January 1990, with the receipt date for applications in April. It is expected that the award will be made in September 1990.

Question. What kind of research will be undertaken there?

Answer. The request for applications (RFA) for the third Learning Disabilities Center contained suggestions that this Center develop a rare event registry that could be used to accumulate adequate sample sizes for the study of infrequently occurring forms of learning disabilities. In addition, the RFA emphasizes the need for improved studies of neurobiological function, higher nervous system organization, and instructional intervention.

PEDIATRIC AIDS

Question. The Committee is aware of the problems concerned with accurate, early diagnosis of AIDS infection in infants who have contracted the disease before birth from their mothers. What progress has the NICHD made in the area of early diagnosis?

Answer. Children born to HIV-infected mothers are at risk of being infected with the human immunodeficiency virus during pregnancy or delivery. Unfortunately, the tests most widely used in diagnosing HIV infection in adults, i.e., those directed at antibody detection, are not useful in distinguishing an infected infant from an uninfected infant. This is because all infants born to infected mothers carry the mothers' antibodies against HIV, antibodies they acquired passively from the mother. These passively-acquired antibodies may persist in the infant's body for up to 18 months. Thus, using the current diagnostic tests, all infants born to infected mothers would initially test positive for HIV antibody, and some would continue to test positive for antibody for up to 18 months. A study jointly conducted by the NICHD and the National Cancer Institute has demonstrated that approximately one out of every three infants born to infected mothers will actually be infected themselves. This relatively substantial risk--together with recent findings that early initiation of treatment in infected individuals leads to prolongation of life, longer symptom-free periods, or periods without progression of disease--makes the solution to the problem of early diagnosis of HIV in infants a very pressing one. That is, if we can improve our methods of diagnosing HIV infection, we will be able to do two things. First, we will be able to increase the efficiency of our clinical trials in newborns because we will be able to focus our attention and resources on infants who are infected. As it stands now, trials in newborns will involve treating both infected and uninfected infants. Second, if we can identify infected infants early and we can also identify a treatment which is beneficial to infants in the earliest stages of infection, we might considerably mitigate the pain and suffering of literally thousands of infants. Clearly, improved methods of the early diagnosis of HIV infection in newborns and infants must be developed. In order to stimulate research in this important area, the NICHD issued a request for applications (RFA) and has awarded six grants in FY 1990 which are focused on solving this problem.

VACCINE DEVELOPMENT

Question. What progress are you making on the testing of the new vaccines that we have heard about, especially the NICHD pertussis and H. influenzae vaccines?

Answer. Substantial progress has been made in advancing both vaccines. Regarding pertussis, studies in Sweden for safety and immunogenicity with NICHD pertussis toxoid vaccine are under way. Immunization is complete, with no adverse reactions, and serological studies are in progress. In addition, a contract is in place to support preliminary and logistic planning for the efficacy trial. Immunization should begin about October 1. The vaccine for this trial will be made under contract by AMVAX, an American vaccine manufacturer, under a license to use the U.S. Government patent for the vaccine. A large scale U.S. trial of the NICHD pertussis toxoid vaccine is currently being planned.

Regarding the NICHD H. influenzae type b conjugate vaccine, a contract is in place for a three-year trial in Charlotte, North Carolina. It is anticipated that the trial will show that we can safely and effectively immunize infants under six months of age against infections with this organism.

CONTENT OF PRENATAL CARE

Question. The Public Health Service Expert Panel on the Content of Prenatal Care identified several gaps in our knowledge of this subject. What research should be undertaken to fill these gaps?

Answer. The panel found that studies were lacking in many aspects of prenatal care and recommended that research be initiated in the following six areas: (1) preconception care; (2) risk assessment activities and data collection systems; (3) health promotion activities--specifically, counseling to promote and support healthful behavior, general knowledge of pregnancy and parenting, and information on proposed care; (4) optimal schedule of visits to physician considering the differing needs of healthy women and women in a medical or psychosocial risk category; (5) interventions to reduce psychosocial risk--specifically, substance abuse counseling and referral to treatment, food assistance and referral, home visits, and social and financial resources; (6) interventions to reduce medical risk--specifically, preeclampsia, infection (especially gonorrhea and HIV), intrauterine growth retardation, genetic and congenital disorders, preterm and postterm birth, and diabetes.

AGRICULTURAL USE OF REPRODUCTION RESEARCH

Question. Are there any examples, Dr. Alexander, of research findings in reproduction, supported by your Institute, that have applicability in agriculture?

Answer. A number of the research projects supported by this Institute have led to improvements in agricultural technology. An important application of the discovery of methods to create transgenic animals, for example, has been the insertion of specific genes into animals to enhance breeding capability, increase disease resistance, and improve the production of milk and lean, tender meat. A related application makes it possible to insert engineered genes into domestic livestock to produce valuable pharmaceutical products. Where such products are secreted in milk, for example, they can be isolated in high purity and large amounts. Other applications of research on reproduction that have proved useful in agriculture are treatments to induce artificial breeding seasons, which increase reproduction; the use of superovulation, in vitro fertilization, and the transfer of embryos from high-quality animals to other domestic livestock; and, most recently, the identification of molecules that can improve pregnancy rates and reduce miscarriages and stillborn births in domestic animals.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

CHILD HEALTH RESEARCH CENTERS

Question. Dr. Alexander, I understand that the Institute has responded favorably to the Subcommittee's recommendation to consider establishing a center grant program for child health research. Would you explain briefly what action the Institute has taken concerning this matter?

Answer. The NICHD has developed guidelines for establishing and operating a program of child health research centers. To announce the availability of funds for this program, the Institute issued a request for applications (RFA) on January 5, 1990. Over 130 copies of the RFA have been distributed in response to inquiries, and at least 25 strong applications are anticipated. The deadline for receipt of applications is April 23, 1990, with review scheduled to begin in July. It is expected that final awards will be made in September 1990.

Question. How many centers does the NICHD anticipate funding in fiscal year 1990? Does the President's budget include funding for any additional centers in 1991?

Answer. The NICHD expects that six child health research centers will be funded in FY 1990. The FY 1991 President's budget does not include funds for any additional centers.

Question. I understand that a central purpose of this program was to expand capacity for pediatric research by using the funds as "seed money" to build a foundation of institutional support. How are you ensuring that emerging programs, particularly those at children's hospitals and clinical centers, have a competitive shot at these funds?

Answer. Child health research center awards will be made only to children's hospitals or departments of pediatrics at medical schools. The announcement of the availability of funds for these centers was published in the NIH Guide to Grants and Contracts, which is sent to research institutions throughout the United States. In addition, copies of the announcement were sent to all medical school chairpersons of pediatrics, and NICHD staff have provided telephone counsel on application preparation to about fifty institutions.

The review guidelines for the center grants competition establish scientific merit of the research program as a primary criterion. In addition, however, there are several criteria which could increase the competitiveness of institutions with emerging programs. These factors include relevance of the theme or area of emphasis of the center to programmatic needs of the NICHD, institutional commitment to the requirements of the program, probable impact of the center on pediatric research at the grantee institution and in the local medical environment, and efforts to develop novel mechanisms for recruiting candidates for support from groups (such as women and minorities) under-represented in pediatric research.

Question. If this Subcommittee could fully fund the new centers program, how much would be required in FY '91, and how many centers would it fund?

Answer. The FY 1991 President's budget provides approximately $1,882,000 for the continuation of the six child health research centers established in FY 1990. Full funding of the program in FY 1991 would require an additional $4,118,000. This amount would eliminate the downward negotiations in awards for the six existing centers and allow for the establishment of 9 additional centers, bringing the total number of centers to 15.

INFANT MORTALITY

Question. Dr. Alexander, while I understand the United States is making progress on reducing the infant mortality rate, it still ranks poorly compared to other developed nations and continues to have a large disparity between infant mortality rates for blacks and whites. Does the fiscal year 1991 budget include funds to broaden the Institute's research activities on infant mortality?

Answer. The Institute's initiative on the prevention of low birth weight and infant mortality will continue to be the number one priority in FY 1991. The budget request includes approximately $61.4 million to continue the research effort in this area at essentially the same level of activity as in FY 1990.

Question. What was the Institute's original budget request to the Public Health Service and how much was assumed for infant mortality research? How does this compare to the budget before the Subcommittee today?

Answer. The Institute's original budget request was submitted to NIH and totalled $712.5 million. Of that amount, approximately $96 million was allocated to infant mortality research, compared with $61.4 million in the FY 1991 President's budget.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

STATEMENT OF DR. DAVID P. RALL, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Dr. Rall? We have your budget request which is $235,790,000, an increase of $6.56 million.

One of the things I would like to discuss with you is the establishment of a research center for health effects of agricultural chemicals. We will discuss that later, but please proceed.

OPENING REMARKS

Dr. RALL. Thank you, Mr. Chairman. It is a pleasure to be here. NIEHS, by studying those factors in the environment that affect human health, provides information necessary to prevent diseases, either through education of the patient, the public, and the physician; or to permit intelligent and rational health regulations.

I would like to present four interesting new research findings and describe two or three ongoing efforts. First of all, in air pollution, which is a critical problem with the Clean Air Act about to be reauthorized, one of the primary criteria contaminants is ozone.

OZONE

Our grantees have shown in very elegant studies that ozone at currently permitted levels injures the lung and decreases pulmonary function in school children in summer camps, and this is perfectly documented with clear correlation between the decrease in pulmonary function and the increase in ambient ozone levels above the criteria.

Second, I have talked often about lead before this committee and the recent report by Dr. Needleman that lead exposure 10 or 15 years ago in young children at levels which are low to moderate. Of those children, he has now followed up a great number of them.

They are six to seven times less likely to finish high school and to have reading disabilities, a very devastating outcome.

CHEMICAL TESTING PROGRAM

In our chemical testing program, we studied one of the primary explosives that is used extensively, not only by the Armed Forces but by civilian construction workers, tetranitromethane which is an incredibly potent carcinogen in mice and rats, and we have so informed the regulatory authorities.

KIDNEY DISEASE

The last new finding refers to kidney disease and I discussed this a little bit last year. End-stage renal disease costs the U.S. Government about $3.4 billion a year. We started out with the premise that there were certain environmental, occupational, and lifestyle factors that might be associated with the cause of renal disease.

We have not gotten to those factors yet, but we have turned up some very interesting and very important findings. First we looked at nonprescription analgesics which have long been suspected of causing kidney damage.

We found first that aspirin has no affect on kidney disease which is very good to know. Second, we found that acetaminophen which is a very common over-the-counter drug if taken daily by patients—now the package insert says only take daily for 2 weeks—this is daily for over a year, increases the chances of end-stage renal disease at least threefold.

And if patients would just take their Tylenol or those other over-the-counter drugs as the package label says, it could cut down a significant amount of end-stage renal disease.

We are currently looking at the nonsteroidal anti-inflammatory agents such as ibuprofen and the results are a little early but it looks, particularly in elderly males, that there is a striking increase in renal disease. And as I said, I hope next year we will be able to talk about lifestyle, diet, occupational, and environmental factors.

But if the findings with simply acetaminophen are translated and the public understands them, there can be a significant saving right now.

AIDS DRUGS

In terms of our ongoing studies, we do study many of the AIDS drugs for perinatalteratology and toxic effects in young animals as a supplement to the clinical experience, and we think it is important that this be done, and in as timely a fashion as possible.

RADON

Our study on the effects of radon in about 4,500 people are well underway and in 2 or 3 years we hope to have what is probably the best study on the effects of radon in the home.

AGRICULTURAL ENVIRONMENTAL HEALTH

We listened, we understood, and we followed up on our discussion at this meeting last year. We are holding a conference on environmental health and agriculture and farm communities in July, and we will explore many of these issues. We anticipate we will be able to establish a center in agricultural health late this summer.

Thank you very much. I would be pleased to answer any questions.

[The statement follows:]

STATEMENT OF DR. DAVID P. RALL

The National Institute of Environmental Health Sciences (NIEHS) leads the nation and the world in basic research into the human health effects of environmental exposures.

We take so much in the environment for granted; we assume the necessities of life will always be there for us. As we move into the final decade of the 20th Century and toward a new millenium, we know of some things that will persist. We must have air to breathe. In general, we would die in less than 10 minutes without air. We would die after about three days without water to drink.

Beyond these most essential requirements of human life, we need food, shelter, and places to work to earn the food and shelter. Each of these is a part of the human environment. Each affects human health, and may affect health in a number of ways. Our quest for the necessities of life has altered our environment in ways that have imperiled some of these necessities themselves.

Much of what we understand today about the human health impacts of human activities in the environment, the interaction of environmental agents and human health, has been developed through the basic research programs of the National Institute of Environmental Health Sciences. Many committee members will recall that asbestos was one of the first research topics I brought to you, and it came up again and again. Asbestos is still with us, but we have a much better understanding today of its health effects, because of NIEHS research.

Our programs address the information gaps of both old and new environmental public health challenges. Research we support continues to expand our knowledge about lead, one of the oldest human-spread environmental contaminants. Our recent conference on the potential impacts of global warming on humen health was the first to probe that emerging set of questions.

We are only now beginning to understand the human health dimensions of the way we use and dispose of our resources-- in the air, the water, or the land.

NIEHS-supported scientists studying the effects of air pollutants on human health have identified both key air pollutants and lung damage that exposure to pollutants, alone and in combination, can cause. Ground-level ozone has been confirmed as a factor in lung damage in studies of healthy youngsters. NIEHS is also pursuing efforts to define the effects of depleted stratospheric ozone on human immune systems. That association stems from more ultraviolet light reaching the earth when the ozone shield is depleted. A portion of our budget request will support continued efforts toward defining and understanding the human health effects of air pollution, including the large study of indoor radon exposure we told you of a year ago.

The human ability to produce new chemicals, like those that have been used to grow larger crops of food and fiber, has outstripped our ability to anticipate and avoid unnecessary exposure to the chemicals both directly and through various paths. A portion of our budget request will go to projects studying the human health effects of pesticides and to developing safer approaches, from the human perspective, to controlling pests.

The recent report on the long-term effects of lead, an early and continuing topic of research supported by NIEHS, indicates that the social cost of human exposure to lead may grow with time as those damaged early in life continue to falter and may be labeled slow. The damage from lead is not confined only to the well-characterized, early effects of lowered mental function and, in the heavily exposed, organic damage and seizures. New NIEHS initiatives include a study of the way lead is transferred from mother to fetus, the way the body stores lead over time, better methods for measuring lead levels in humans, and development of improved therapies for those with high lead levels.

When we first discussed the need to identify potential human health effects of global warming, it was not obvious how sparse the information base was. Following the NIEHS conference on global warming and human health, that lack is much clearer. So are some considerations for public health, from possible new ranges for insects that carry disease to the effects of altered nutrition from altered food crop availability, heat stress, and potential effects of new products and processes used to try to alter the pace of change. These were among the topics at our conference, the first to address that subject specifically.

Meanwhile, our scientists are studying today's challenges in health effects and diseases linked to environmental exposures, seeking things we might do now to ease the burden of such disease.

I want to report on the first results of an NIEHS epidemiological study on the environmental factors that may contribute to end stage renal disease.

Kidney disease is an expensive national public health challenge. Recent data from the national renal disease information base indicates dialysis cost the nation $3.5 billion in 1988. The cost in human suffering and economic productivity for those with end stage renal disease has not been quantified.

The incidence of kidney disease is higher in the southeast than in other regions of the country and there have been a number of theories about why this is so. Our epidemiologists designed a study to look at what is really going on. This long-term study has focused on identifying preventable causes of kidney disease.

Our investigators sorted through the well-known associations with hypertension, diabetes and other systemic diseases. Among the environmental suspects are solvents and other chemicals; lead, cadmium, and other metals; and a variety of drugs including nonsteroidal anti-inflammatory drugs, other analgesics, antibiotics, high blood pressure medications and diuretics. Environmental influences as contributors to renal disease for people who have high blood pressure or diabetes are also being considered.

The study found that daily users of acetaminophen analgesics had three times the risk of developing renal disease as those without this pattern of use, and the data supported a dose response. Daily use of phenacetin, a related compound removed from the over-the-counter market some time ago, was linked to a five-fold increase in risk for kidney disease. Daily users of other non-aspirin, nonsteroidal anti-inflammatory drugs were twice as likely as non-users to develop chronic renal disease, but the risk was concentrated among older men, who had 10 times the risk of non-users.

Still being analyzed are the possible influences of caffeine, alcohol, cola beverages, and related lifestyle factors.

The molecular basis of cancer evidently involves two opposing forces: oncogenes which lead to cancer and suppressor genes which inhibit cancer. Both sides of this equation are under intensive investigation at NIEHS. A single human chromosome, chromosome number 1, seems to determine whether or not tumor cells continue unlimited growth in culture or grow old and die. These studies may provide a molecular basis for tumor suppression. A novel oncogene is activated in human mesoltheliomas, a highly malignant tumor associated with exposure to asbestos. Future efforts could lead to the development of a diagnostic marker for either preclinical disease or exposure to other toxic fibers, and, possibly, to potential treatments.

We continue to share information and foster communication among scientists, policymakers and the public about where the need for more and better information is greatest. Two significant examples of this effort may be seen in meetings during 1989 on the Alaskan oil spill and on methylmercury.

The oil spill conference brought up, for the first time in such a forum, questions about potential human health effects of exposure to the crude oil in Prince William Sound. In addition to effects on wildlife and aquatic life that may have implications for people, conference participants identified exposures with potential health consequences for cleanup workers and those who live near the oiled shorelines. Short- and long-term physical, medical, and psychological impacts of the spill and its aftermath were among the considerations.

Mercury, in its toxic methylmercury form, is emerging as a more ubiquitous environmental agent than had been realized. In the NIEHS conference, scientists discussed emerging evidence of adverse effects on the unborn at very low levels of maternal exposure to methylmercury. Recent studies have examined mercury fallout into lakes after long-distance air transport, the ensuing change in chemical form--methylation-- and subsequent mercury in food fish that may find their way to the table. Scientists noted that lakes with acid water seem to have more methylmercury in the water and in the fish. Another agency's study, reported in January, noted the increasing numbers of acidified U.S. lakes, especially in the East and the upper Midwest. Brazil offers an example of the variety of sources for mercury emissions to the global winds. Brazil's massive chloralkali paper processing plants and an entrepreneurial gold mining industry where blowtorches are used to separate gold from dirt and mercury account for large quantities of mercury that eventually contaminate lakes and rivers and the fish in them.

I am pleased to report that we are beginning an Environmental and Occupational Medicine Academic Awards program with the dual purposes of improving the quality of environmental and occupational medicine curricula and of fostering research and careers in environmental and occupational medicine. This effort addresses concerns outlined in an Institute of Medicine report. For this award, the term environmental and occupational medicine is used to define the medical area that has special concern for the development and application of knowledge for the diagnosis and treatment of adverse human health effects from environmental and occupational exposures to environmental agents.

And finally, the National Toxicology Program's testing program produced 27 printed technical reports on chemicals in fiscal 1989, and had 21 technical reports and eight toxicity studies peer reviewed. From that program, which is considered the world standard for such testing, NTP issued the final report on tetranitromethane, a rocket propellant and explosive that rapidly produced many lung tumors in test animals. The NTP had alerted the Department of Defense, the agency responsible for plants where the chemical is used, NIOSH and OSHA when the early results appeared.

Other chemicals positive for cancer in NTP tests included glycidol, a stabilizer in vinyl polymers and an additive for oils and hydraulic fluids; nalidixic acid, a pharmaceutical ingredient which caused cancers in rats but not in mice; 4-vinyl-1-cyclohexane diepoxide, used in epoxy resins, which caused cancer in all exposures-- male and female rats, male and female mice; and hydroquinone, a metabolite of benzene and a chemical used in photography. On the other hand, chemicals that did not cause cancer in NTP tests included amphetamine, which is a pharmaceutical, the riot control agent mace, and vinyl toluene, an important industrial chemical.

Mr. Chairman, the budget request for the National Institute of Environmental Health Sciences is $235,792,000. I would be pleased to answer your questions.

BIOGRAPHY OF DR. DAVID P. RALL

August 3, 1926. Aurora, Illinois

Education: B.S. North Central College, 1946; M.S. (Pharmacology), Northwestern University, 1948; M.D., Northwestern University School of Medicine, 1951; Ph.D. (Pharmacology), Northwestern University, 1951.

Professional History: 1952-53, Intern, Bellevue Hospital. 1953-58, Scientist, Laboratory of Chemical Pharmacology, National Cancer Institute. 1958-63, Head, Clinical Pharmacology and Experimental Therapeutics Service, General Medicine Branch, National Cancer Institute. 1963-69, Chief, Laboratory of Chemical Pharmacology, National Cancer Institute. 1966-71, Associate Scientific Director for Experimental Therapeutics, National Cancer Institute. 1971-present, Assistant Surgeon General, USPHS.

Professional Organizations: American Association for the Advancement of Science, American Association for Cancer Research, American Public Health Association, American Society for Clinical Investigation, American Society for Pharmacology and Experimental Therapeutics, Society for Occupational and Environmental Health, Society for Risk Analysis, Society of Toxicology.

Honors, Awards: Editorial Board, Proceedings of the Society for Experimental Biology and Medicine, 1962-65. Member, National Institutes of Health Chemotherapy Study Section, 1965-67. PHS Meritorious Service Medal, 1966. Chairman, National Institute of General Medical Science Pharmacology Toxicology Review Committee, 1967-69. Editorial Board, Pharmacological Reviews, 1969-72. Chairman, DHEW Departmental Committee on Drug Research and Regulations, 1970. Associate Editor, Cancer Research, 1970-74. Chairman, OST-CEQ Ad Hoc Committee on Environmental Health Research, 1971-72. Adjunct Professor, University of North Carolina, Chapel Hill, 1972-present. US Coordinator, Environmental Health Program, US-USSR Health Exchange Agreement, 1972-present. Chairman, DHHS Committee to Coordinate Environmental and Related Programs, 1973-1985. Editorial Board, Archives of Environmental Health, 1973-76. Associate Editor, Journal of Toxicology and Environmental Health, 1974-78. DHEW Distinguished Service Medal, 1975. Member, DHEW Secretary's Review Panel on New Drug Regulation, 1975-76. Member, NAS Safe Drinking Water Committee, 1975-1977. Chairman, Committee on Health and Environmental Effects of Increased Coal Utilization, 1977-78. Member, Institute of Medicine, 1979-present. Editorial Board, American Journal of Industrial Medicine, 1980-present. Member, WHO Programme Advisory Committee, 1980-present; Chairman, 1980-81. Editorial Board, Risk Analysis, 1981-present. Editorial Board, Regulatory Toxicology and Pharmacology, 1981-present. Arnold J. Lehman Award, Society of Toxicology, 1983. Member, US Delegation to the US-Japan Cooperative Medical Science Program Committee, 1984-present. Member, Committee on Council Affairs, American Association for the Advancement of Science, 1986-88. World Health Organization "Health for All 2000" medal, 1988. Ramazzini Award, 1989.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator Harkin. Dr. Rall, thank you very much for your statement. We will get back to the chemicals very shortly. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

LOW LEVEL EXPOSURES

Question. What are the major research needs if we are to get a better handle on the threats of really low level exposures like lead, mercury, global warming, farm chemicals, etc?

Answer. The metals toxicity issue includes development of better assays for really low levels of metals such as lead, cadmium, and mercury, especially in tissues and in mixtures. We need to follow some of our previously studied lead-exposed populations more extensively to determine if the neurological effects ever disappear.

The key research needs in the area of global warming are to evaluate the toxicity of the most likely alternative fuels and chlorofluorocarbon replacements. Since a main health effect of global warming is increased air pollution, we need to develop new biomarkers for lung effects. Also, immunosuppression by excess ultraviolet light exposure needs to be studied in humans since the data is highly suggestive that animals exposed to ultraviolet light are more susceptible to bacteria and viruses.

Finally we need better biomarkers in the area of farm chemicals to identify cancer, neurotoxicological and reproductive effects. Some of the oncogene and transgenic mouse work we are doing would apply to identifying cancer effects of specific exposures. Some of the pesticides can be studied by using the neurotoxicological tests developed for metals toxicity, and the tests we developed for early pregnancy loss might tell us a great deal about farm chemical reproductive toxicology. Overall, our knowledge of the toxicities from these areas would benefit clearly from additional epidemiology. Also development of additional biomarkers is necessary in all of these areas.

ALASKAN OIL SPILL

Question. The Alaskan Oil Spill generated much concern for the ecology of Prince William Sound as well as potential impacts on human health. What are the potential human health implications of this spill and what are related research needs?

Answer. Immediately following the March 1989 spill, NIEHS scientists began a review of available toxicological data concerning crude oil and weathered products. NIEHS sponsored and organized a conference on "The Alaskan Oil Spill and Human Health" which was held in Seattle during July 28-30, 1989. This conference was well attended and included sessions dealing with toxicity of crude, environmental fact and distribution of spilled crude, human exposures and health effects and strategies for prevention of human exposures.

This conference pointed to a significant lack of solid scientific data concerning toxicity of crude oil and weathered products, bioaccumulation of toxic components, including metals, and the potential for long-term exposure through the human food chain. In fact, very few data on the contamination of sea life were presented, suggesting that the extent of contamination of food fish, etc. was not known. Much more health research is needed. Most importantly, the scientific community must develop action plans which will allow collection of vital data during the early phases of any future oil spills.

TREATMENT OF HAZARDOUS WASTES

Question. Some people consider biological treatment of hazardous wastes to have potential in the remediation of some Superfund sites and other hazardous waste situations. What are your thoughts on this technology as it relates to your mission, and are you supporting its development as a means of reducing the amount and toxicity of hazardous substances?

Answer. In 1986 the NIEHS had an opportunity to expand its traditional basic biomedical research mission when it was given authority and funds under the Superfund Amendments and Reauthorization Act (SARA) to establish a multidisciplinary, university-based research program to expand the base of knowledge related to the human health aspects of hazardous wastes. One of the aims of this program is the development of biological treatment technologies to decrease the risks associated with environmental pollutants.

For example, recent research results indicate that it may be possible to modify _in situ_ the environment of a large variety of bacteria present at a contaminated site in order to optimize microbial degradation. It has been shown that, in these contaminated regions, bacteria are present which have the ability to completely degrade specific compounds at reduced or minimal oxygen concentrations. Under simulated environmental conditions, this activity has now been demonstrated in pure bacterial cultures. This discovery suggests that significant bioremediation of contaminants may be promoted _in situ_ by the addition of simple nutrients to stimulate bacterial degradation as opposed to the usual above ground remediation techniques which are more expensive.

In situations where relevant bacterial strains are not resident, naturally occurring strains from other sites might be seeded to promote _in situ_ bioremediation. Other approaches include the design of new bacterial species or the use of fungi, such as the white rot fungus. The further refinement and development of such cost effective technologies should allow for more cleanup activities with minimal perturbation of the sites.

I might add that on April 9-10, 1990, NIEHS will be sponsoring a conference at Utah State University entitled "Biodegradation of Hazardous Wastes." An up-to-date review of this field will be presented, and the meeting will provide a forum to discuss this technology's impact on human health and the environment.

OZONE

Question. Can you explain why we seem to want one kind of ozone, the kind we're losing high in the atmosphere, and don't want the kind of ozone that goes with smog?

Answer. Ozone in the stratosphere provides a kind of shield against ultraviolet light coming from the sun by taking up the light's energy in a chemical reaction, keeping it from reaching the earth. We are concerned that more ultraviolet light reaching the earth will cause increases in the number of skin cancers and cataracts. Ozone at ground level, on the other hand, is a lung and eye irritant, and it acts with other air pollutants to damage lung function in people exposed to the pollution soup.

REGULATORY ACTIONS

Question. To what extent do the results of NIEHS research result in federal regulatory actions to protect the public health?

Answer. Since 1980, the NIEHS' National Toxicology Program (NTP) research results on several hundred chemical substances have been cited in 179 regulatory actions in the Federal Register. Seventy-four percent of these citations were by the Environmental Protection Agency, 13 percent by the Food and Drug Administration, 9 percent by the Occupational Safety and Health Administration, and the remaining 4 percent by various other agencies.

TOXIC RELEASE INVENTORY

Question. The EPA Toxic Release Inventory indicates substantial contamination of the environment by industrial emissions in every state. What is NIEHS doing to evaluate the hazards to human health?

Answer. As the component of NIH responsible for research on environmental health, NIEHS is aware of the environmental contamination across the nation. The Toxic Release Inventory (TRI) confirmed the magnitude of the problem -- 21.6 billion pounds of toxic substances released into the environment or transferred to treatment sites in the U.S. in 1987 -- and alerted the public to potential health hazards in their communities. NIEHS serves as the focus within NIH for research on the adverse health effects of environmental substances including industrial emissions. The research includes a research and training grants program in universities and an intramural research program at NIEHS laboratories designed to obtain fundamental knowledge about the ways that chemical substances affect health. NIEHS is also the organizational home of the National Toxicology Program which conducts studies to identify and characterize the toxicity of substances in the environment so as to provide a rational basis for preventing or diminishing exposure to hazardous chemicals.

Recent research accomplishments include: results from Harvard School of Public Health's Six and Twenty-four Cities Surveys, designed to study the effects of ambient sulfur and particulate matter and acidic and fine particulate pollutants, respectively, on respiratory health, have shown a relationship between respiratory symptoms and total suspended particulates and strongly suggest that acid aerosol concentrations may more strongly predict respiratory illness and symptoms than the current criteria pollutants. When completed, these two studies will provide the largest data base of its kind and will be critical to future standard setting and in implementing acid rain programs. Other work supported by the Institute is directed towards testing the hypothesis that observed levels of ambient particulates, especially particulates in the fine respirable fraction, are associated with adverse respiratory health effects. This study is being conducted in a coastal pulpmill town where the particulates are also impregnated with salt. Few of the substances on the TRI list have been evaluated for late-developing effects such as cancer. The NTP has long-term toxicologic studies in progress or completed on 10 of the 25 chemicals with the largest national release rates, including methanol, toluene, acetone, and xylene.

MINORITY HEALTH

Question. As you know, minority issues are a major concern with the Administration and the Department of Health and Human Services. Can you give us an example of the type of research supported by the NIEHS that focuses on minority health?

Answer. Yes. We share in the concern that a large number of minority and low income Americans suffer from preventable illnesses and premature mortality. Lead poisoning in children is a dramatic example of a disproportionate number of poor and minority citizens suffering from an entirely preventable, but wide-spread environmental illness. Recent regulations aimed at removing lead from gasoline have resulted in a decline in blood lead levels in American children. But high levels of lead have accumulated in the dusts and bare soils in the yards and play grounds of many inner cities where the poorest children play. The Agency for Toxic Substances and Disease Registry noted in a 1988 report to Congress that between 1.8 and 2.0 million children live in the six million housing units with peeling and chipping lead-based paint.

Exposure to lead in the environment exacts a terrible toll on the health of the children who, by virtue of their family income, race, and, home environment, are exposed to the hazardous effects of lead on a daily basis. Too often this damage begins with exposure to lead in the blood shared by the fetus with its mother before birth.

At NIEHS, we spend about $7 million per year in research studies designed to better understand the mechanisms by which lead damages the nervous system, to identify persons and groups who are most sensitive and vulnerable to the subtle effects of lead poisoning, to design more accurate and cost-effective diagnostic techniques, and to identify safe and effective therapeutic drugs and methods for use by obstetricians and pediatricians.

Our toxicologic research studies have identified other extremely hazardous substances to which minority and poor people are routinely exposed. The chemical, 1, 3- butadiene is an example. This chemical has dozens of uses in industrial processes and billions of pounds have been used each year. The greatest exposures to 1, 3- butadiene occurred among predominantly minority, least highly skilled rubber manufacturing workers. This chemical was tested by NIEHS for the National Toxicology Program in long-term, 2 year, rodent studies and was found to be among the most toxic substances ever tested. Industry and government reacted immediately to reduce average exposure levels in manufacturing plants by 100 to 1,000 times the pre-study "normal" levels and the risk of cancer to the workers exposed to 1, 3- butadiene was similarly reduced.

These are only two examples of NIEHS research which yields information of critical importance to the health of low income and minority Americans. We are responding to the leadership shown by the Congress and by Secretary Sullivan to assure that the preventable environmental health problems of the most needy are given highest attention and priority in our research efforts.

TOXICOLOGICAL PROBLEMS OF PESTICIDE EXPOSURE

Question. It is projected that the global sales of pesticides will exceed $50 billion in 1990 and it is estimated that in the U.S. 2.6 million pounds of pesticides are applied to our fields each year. Obviously, these chemicals may contribute to human health problems. Of particular concern is the exposure of minority populations which make up the largest segment of the migrant work force, of children, and of the developing fetus. Is your Institute addressing the toxicological problems of pesticide exposure?

Answer. For many years NIEHS has focused its research resources on problems related to pesticides, from studies to develop safer agents to the health effects in people and experimental animals. In this effort, pesticide exposure during key developmental and growth periods is of major concern.

We have ongoing research related to pesticide exposure and spontaneous abortion in the San Joaquin Valley of California where pesticide usage is heavy and a large segment of the work force is Hispanic. Attempts are being made to identify which of the major pesticide classes are more strongly correlated with spontaneous abortion and fetal death.

We also support a number of laboratory-based studies aimed at the mechanisms of toxicity of these agents. For example, in research on mechanisms in the placenta for detoxifying chemicals, investigators have found that in some cases the placenta actually forms more potent metabolites and does not always protect the fetus from harm. The chemicals can cause detrimental effects on the maturation of the nervous system, the immune system, the endocrine system, and in some cases growth retardation has been observed.

NIEHS-supported research has shown that many of these pesticides are fat soluble and are passed from mothers to infants during breast feeding. Thus, more research is needed on how infants handle such toxicants, as they have little in the way of fat reservoirs and many of the enzyme detoxification systems are immature. Hence, children are especially vulnerable at a time when they are receiving perhaps the greatest exposure through contamination of their food sources.

Finally, but importantly, we are concerned by the NAS - NRC testing needs study report and the report of the Agriculture subcommittee that only relatively small portions of pesticides have been adequately tested, particularly for carcinogenicity.

SAN JOAQUIN VALLEY

Question. Tell us more about why NIEHS is supporting the pesticides and fetal death study in the San Joaquin Valley -- what can you learn?

Answer. NIEHS has long supported some very basic research on the mechanisms of pesticides. This study is specifically looking at the effect of exposure to pesticides during pregnancy. So far, the scientists have learned that it is possible to link pesticide application data and the mother's place of residence. They have also determined the specific classes of pesticides involved. Now they are analyzing the data to see which, if any, of these exposures may correlate with spontaneous abortion and fetal death.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

LEAD

Question. Dr. Rall, as you may know, Philadelphia and Pittsburgh both have pockets of old public housing projects which still have a lot of lead based paint. Has the Institute done any research in the area of lead poisoning?

Answer. The NIEHS has a very active program to investigate lead effects. During fiscal year 1989, NIEHS funding of approximately $7 million supported 34 research grants and center grants that included a component on lead research. We continued to support research on human health effects of exposure to low levels of lead during a period when many believed that additional study would not have yielded much important information. Our studies have included three prospective longitudinal studies on the effects of lead on learning abilities and neurophysiological functioning among children. The NIEHS supported studies include one of children from low social and economic status in Cincinnati, one of children of upper income professional families in Boston, and a study in Yugoslavia that involved evaluation of mothers and infants in a village near an industry working with lead and in a control village. NIEHS has also sponsored the 11-year follow-up of children, who are now approximately 19 years of age, conducted by Dr. Needleman of the University of Pittsburgh School of Medicine, in which he identified the persistence of a lead effect in academic performance. This performance was judged by likelihood of graduating from high school and reading levels.

Lead exposures during pregnancy are also a cause for concern. Lead readily crosses the placenta and accumulates in fetal tissues. Currently, NIEHS is studying whether current environmental lead exposures---for example, from diet, air, or water---dominate transfer to the fetus or if body stores of lead---for example, bone lead---will determine the quantity of lead transferred. Because the effects of in utero lead exposures are persistent it is clearly necessary to minimize transfer of lead during pregnancy. NIEHS is sponsoring two studies under research contracts, one in Australia among women living near one of the world's largest lead smelters and the other is a laboratory research project with experimental animals. In addition, NIEHS sponsors a substantial effort in research on mechanisms through which lead produces adverse effects on human health.

One component on NIEHS research is the National Toxicology Program. The NTP is investigating the biological availability of lead oxide, lead sulfide and galena ore based on laboratory studies.

Question. What have been the findings?

Answer. In both the Cincinnati and Boston studies, low to moderate exposures to lead were associated with decreased performances on IQ tests, with changes in behavior and body balance performances, and other indicators of subtle neurologic damage such as pattern recognition. The Yugoslav studies were of a much more seriously, heavily exposed and damaged population of children and adults with the classical signs of lead poisonings. In all studies, the effects of low level lead exposures were most dramatic in children, but moderate to high exposures to lead were seen to effect adults. High lead exposures give blood lead concentrations in excess of 50 micrograms per deciliter, moderate exposures give blood lead concentrations of 25 to 50 micrograms per deciliter, and low lead exposures give blood lead concentrations of 10 to 25 micrograms per deciliter.

Question. Is this a significant problem impacting the health of our nation's children?

Answer. The answer here is definitely yes. The problem is seen in both central urban and suburban areas. Millions of houses and children are involved here if the "adverse effect" level is taken as any child with blood lead concentrations greater than 10 micrograms per deciliter---as our most recent research has indicated.

Question. Is it limited to children alone?

Answer. No, it is not, although children have been the most intensively studied in our recent work. The problem in adults is to sort out the contribution of lead versus that of many other similarly acting chemicals or agents---like smoking, alcohol, drugs, other metals, solvents and so forth. Pregnant women and their fetuses are perhaps the biggest "other than children" group affected by even very low lead concentrations and exposures. Adults who perform do-it-yourself restorations of old houses is another large lead affected group because of the lead based paints removed in such restorations.

NUMBER OF NEW LONG-TERM TOXICOLOGY STUDIES

Question. Dr. Rall, I am advised that the Institute generally has sufficient resources to begin long-term toxicology studies on 10 chemicals each year. In your professional judgment, is this level of new starts enough to provide adequate information to safeguard the American people from hazardous chemicals?

Answer. The need for long-term toxicology studies to determine whether exposure to chemical substances might be a health hazard far exceeds the capacity of NIEHS to conduct such studies. A study by the National Research Council of the toxicity testing needs for 65,725 substances in our environment to which there is known or anticipated human exposure revealed that adequate studies for health hazard assessment were available for only 5 percent of food additives, 10 percent of pesticides, 2 percent of cosmetics, 18 percent of drugs, and zero percent of 48,523 chemicals in commerce. The resources to the Institute to address this problem have changed little over the last decade.

Question. How many new studies do you anticipate beginning in FY 1991 and how many did you begin in FY 1990 and FY 1989?

Answer. We anticipate starting 10 additional long-term studies in FY 1991. Thirteen new studies were started in FY 1990 and eight new studies were started in FY 1989.

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

STATEMENT OF DR. PHILIP E. SCHAMBRA, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Dr. Schambra, we have your statement and your budget request is for $16,355,000, and we are interested in hearing about the opportunities for involving more scientists from the Soviet Union and Eastern Europe.

Please proceed.

Dr. SCHAMBRA. Thank you, Mr. Chairman. For over 20 years, the Fogarty International Center [FIC] has served as the international arm of the National Institutes of Health. FIC's efforts have helped propel the NIH to a leading position in international biomedical research.

FIC's mission is to facilitate international collaboration, and the Center accomplishes this with several key undertakings: funding basic research and training; negotiating and administering bilateral and multilateral agreements; and developing policies for creating new opportunities for cooperation. I would like to illustrate these diverse activities with a few examples.

Our research and training programs support United States and foreign scientists at different stages throughout their careers. We believe strongly that international collaboration must reach into the laboratory, giving scientists the chance to work side by side. Our fellowship programs for young foreign investigators and mid-career U.S. researchers supported 128 scientists from countries worldwide in the past fiscal year. Among their achievements is a new diagnostic blood test for the highly infectious dengue fever, which occurs in epidemic proportions in the Caribbean and other tropical regions.

FIC also funded 140 United States and foreign investigators through special AIDS research and training programs. These programs greatly add to the army of scientists able to conduct research on the spread of AIDS and conduct drug and vaccine clinical trials, particularly in developing countries.

Additionally, the Center brings eminent United States and foreign scientists to the NIH for a year of advanced study. These Scholars-in-Residence published more than 60 scientific papers during the past fiscal year. Their studies are breaking new grounds in such areas as neurobiology and vaccine immunology.

In fiscal year 1989, FIC also administered NIH's involvement in 73 formal research agreements with 39 countries and multilateral organizations. For instance, FIC negotiated new technology agreements with Bulgaria and Hungary, and helped the Japanese Government develop its Human Frontier Science Program, a new source of research funds for United States and other investigators. The Center launched a Latin American initiative, which has two main objectives: to facilitate cooperation in new research efforts, such as those on the human genome and neurological diseases; and to increase training opportunities for junior Latin American scientists.

PREPARED STATEMENT

In short, Mr. Chairman, we have had a busy year, one full of scientific advances and new policy initiatives. Such accomplishments promise improved health to people worldwide—a promise fulfilled only by international collaboration.

Our fiscal year 1991 budget request is $16,355,000, and I would be pleased to answer any questions you may have.

[The statement follows:]

STATEMENT OF DR. PHILIP E. SCHAMBRA

The benefits from international cooperation in scientific research stretch back to the origins of modern medicine. They illustrate how much is gained whenever men and women of different cultures and viewpoints congregate.

In the 17th century, for instance, the young English physician William Harvey traveled to Italy's University of Padua, then the world's leading medical research center. There, Harvey studied with the great Italian anatomist Fabricius, who believed blood flows in and out of the heart like the ebb and flow of the tides. Their collaboration incited Harvey, on his return to England, to devise a series of inventive experiments to see if Fabricius was correct. Contrary to Fabricius' views, Harvey found that the heart pumps the blood to circulate throughout the body--a key discovery in the history of medicine. This turning point hinged on two researchers from two nations working together in one laboratory.

As biomedical scientists face the 21st century, such international collaboration is more vital than ever for achieving the advances necessary to improve the health of people worldwide. It is the mission of the Fogarty International Center (FIC) for Advanced Study in the Health Sciences to facilitate such collaboration. For over 20 years, FIC, the international arm of the National Institutes of Health (NIH), has worked to promote worldwide collaboration on many levels--scientist-to-scientist, institute-to-institute, and nation-to-nation.

FIC accomplishes this goal in part through a variety of fellowship and exchange programs that support scientists at every career stage and bring about the kind of dramatic advances made possible by Harvey's sojourn in Italy. I would like to briefly illustrate some of these programs and their rewards.

Our International Research Fellowship (IRF) program brings junior foreign investigators to work in U.S. laboratories. It has supported more than 2,700 scientists from more than 50 developed and developing countries since 1958. In the last fiscal year (FY) alone, FIC funded 90 IRF awards to investigators from 35 countries. Their work has produced such gains as the following examples:

o A new diagnostic blood test for the viral disease dengue fever, a highly infectious illness that occurs in epidemic proportions in the Caribbean and other tropical regions. The new test resulted from collaborative research by an IRF awardee from Thailand and scientists at the University of Massachusetts. Their test uses recombinant DNA technology to detect antibodies to dengue fever in a blood sample. The test is simple and reliable, and will help physicians diagnose the sometimes fatal disease in its early stage. It also will enable epidemiologists to monitor future dengue outbreaks.

o Discovery of a biochemical abnormality in the brain that may play a role in epilepsy. An IRF from Italy, collaborating with scientists at the University of Maryland, found the brain mechanism for producing and releasing quinolinic acid, an amino acid important in transmitting nerve messages. The researchers believe that an abnormal concentration of quinolinic acid in the brain contributes to the development of epilepsy. If so, certain forms of epilepsy may be treatable by correcting the faulty brain mechanism.

The Senior International Fellowship (SIF) program supports more-established U.S. scientists to conduct research overseas with foreign colleagues. Since 1975, the SIF program has funded nearly 650 U.S. scientists; in FY 1989, it awarded fellowships to 38 U.S. investigators. Their studies are making such strides forward as the following:

o Discovery of mechanisms in the brain involved with memory storage. A University of Alabama SIF and scientists at the Australian National University investigated specialized structures that transmit messages as electrical impulses between nerves. Their work may lead to the development of ways to reduce the memory deficits caused by such progressive neurological disorders as Alzheimer's disease.

Finally, Fogarty's Scholars-in-Residence program brings internationally renowned U.S. and foreign scientists to the NIH, where they conduct advanced studies and interact with the Institutes' investigators. In the past fiscal year, these scholars published more than 60 scientific papers on such topics as calcium's role in muscle functions and cardiac failure, and genetic markers for coronary disease susceptibility. Their accomplishments include the following:

o Potential new types of vaccines based on immune-cell manipulation. A scholar from Sweden's University of Stockholm and investigators at the National Institute of Allergy and Infectious Diseases have identified which CD4 and CD8 immune system T cells react to the foreign chemicals or antigens produced by specific malaria parasites. These T cells stimulate the secretion of IL-2 lymphokine, a substance that increases immune system activity, intensifying the body's ability to destroy invading bacteria. The finding will help scientists choose antigens for use in effective malaria vaccines--and perhaps lead to T-cell immunity vaccines for other diseases.

Fogarty also has created special research and training fellowship programs as a response to the global AIDS epidemic, which has spread from its initial risk groups to women and children, particularly those in African and other developing countries. These programs are training much-needed epidemiologists from developing countries, so they can conduct research on the spread of AIDS and perform drug and vaccine clinical trials. In FY 1989, these programs supported 140 participants from 26 countries.

Fogarty's many international activities extend beyond its grant and fellowship support, however. The Center serves as the keystone in guiding Federal Government policymakers and coordinating the 73 formal agreements between the NIH and 39 countries and multilateral organizations, such as the World Health Organization. These efforts include administrating NIH participation in collaborative clinical drug trials and other studies, and fostering new initiatives for international cooperation. These efforts are crucial because of the speed with which new health menaces spread worldwide and the changing political conditions that can open or close doors to collaborative research.

For instance, Fogarty has moved quickly to take advantage of the changes occurring in Eastern Europe, where eased political constraints are creating new opportunities for scientific collaborations. Our efforts in FY 1989 included helping to negotiate a new science and technology agreement between the United States and Hungary. The agreement, proposed by President Bush, targets cooperative projects in medicine and the environment. It also establishes a joint fund to support collaborative scientific research.

Members of our staff also were part of a delegation to Moscow that successfully expanded the U.S.-U.S.S.R. Health Agreement to include NIH collaborations on the human immunodeficiency virus, which causes AIDS, and medical primatology, which deals with the use of primates in medical research.

Western Europe is undergoing dramatic changes, too, and Fogarty has been preparing policy papers for the White House Science Advisor on what the 1992 economic merger will mean for U.S. biomedical research.

Fogarty also has begun a "Latin American Initiative." The initiative's objectives are twofold: to facilitate cooperation in new research efforts, such as those on the human genome and neurological diseases; and to increase training opportunities for junior Latin American scientists.

I have time to mention only two other interesting activities. First, I have agreed to be the NIH coordinator for a Vatican-sponsored conference on the neurosciences, a field whose importance was underscored by congressional legislation making the 1990's the "Decade of the Brain." As coordinator, I will help develop and organize the participation of all of the Institutes.

Finally, our staff helped the Japanese Government and other Economic Summit countries plan and implement the new Human Frontier Science Program, which will support basic research on the brain and molecular biology.

The 1990's promise unprecedented opportunities for collaborative scientific projects. By taking advantage of these opportunities, we can improve the health of Americans and of people worldwide.

Our 1991 budget request is $16,355,000. Mr. Chairman, I am pleased to answer any questions you or your colleagues may have. Thank you.

BIOGRAPHY OF DR. PHILIP E. SCHAMBRA

Birthdate:	November 8, 1934 - Saginaw, Michigan	
Education:	1956 -	B.A., Rice University
	1961 -	Ph.D., Yale University
	1961-1963	Postdoctoral, Institut fuer Strahlenbiologie, Germany
	1964-1966	Postdoctoral, University of California, Berkeley

Professional History:

1956-1958	Research Assistant, Biophysics Department, Yale University.
1958-1961	Predoctoral Fellow, National Cancer Institute, Biophysics Department, Yale University.
1961-1963	Research Associate, Institut fuer Strahlenbiologie, Karlsruhe, Germany.
1964-1965	Instructor, Department of Medical Physics, University of California, Berkeley.
1964-1967	Research Biophysicist, University of California, Berkeley.
1966	Laboratory Director, National Science Foundation Summer Institute in Radiobiology, University of California, Berkeley.
1967-1968	Grants Associate, National Institutes of Health.
1968-1971	Budget Examiner, Office of Management and Budget, Executive Office of the President.
1971-1974	Staff Member, Council on Environmental Quality, Executive Office of the President.
1974-1980	Associate Director for Interagency Programs, National Institute of Environmental Health Sciences, NIH.
1980-1984	Chief, International Coordination and Liaison Branch, Fogarty International Center, NIH.
1984-1988	Science Attache and PHS International Health Representative, U.S. Embassy, New Delhi, India.
1988-	Director, Fogarty International Center, National Institutes of Health

Honors and Awards:

1989	PHS Superior Service Award
1984	NIH Merit Award
1982-1989	Outstanding Performance Ratings
1986-1988	Merit Performance Awards
1987	Secretary DHHS Certificate of Appreciation
1964-1966	NASA Research Fellowship, University of California, Berkeley
1958-1961	National Cancer Institute Fellowship, Yale University

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Dr. Schambra, thank you very much. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

EFFECTS OF GLOBAL WARMING AND OZONE DEPLETION ON HEALTH

Question. As one of its Research Management and Support activities for FY 1991, the FIC is involved in the international planning efforts to address the effects of global warming and ozone depletion on health. How much will be spent in FY 1991 on these activities? Please explain more about the FIC's efforts and the possible effects on worldwide health.

Answer. Our estimate is that FIC will spend approximately $150,000 on these activities in FY 1991. The FIC has conducted a study of "The Need for International Efforts to Address the Potential Health Effects of Atmospheric and Climate Changes." The potential impact of climate change upon human health is of direct concern to the NIH and similar organizations around the world. International cooperation is essential if the potentially harmful health and environmental consequences of global atmospheric and climate change are to be successfully addressed.

The FIC is proposing a commitment of $150,000 to initiate a collaborative project with NIEHS, EPA, the Department of Energy and other national and international institutions, to enable us to support international research related to global warming and ozone depletion. Our initiative will include the following actions:

- o Convening a group of international experts to develop a research agenda to address the potential health effects of atmospheric and climate changes, including impacts on infectious and cardiovascular diseases, and skin cancer;

- o Providing support for the training of researchers and health professionals related to atmospheric and climate changes, including the training of professionals from developing countries to help them address these concerns in their home countries; and

- o Supporting an FIC Scholar-in-Residence to cooperate with NIEHS scientists on this topic.

Among the health concerns related to global warming are: cataracts and retinal degeneration; non-melanoma skin tumors and cutaneous malignant melanoma; weakening of the immune system; and effects on cardiovascular, cerebrovascular, and renal diseases. In addition, there is great concern that global warming will upset the ecosystem, resulting in the appearance of tropical and infectious diseases such as dengue, yellow fever, and St. Louis encephalitis in areas of the United States not currently affected.

It is imperative that international efforts begin now to better understand the health consequences of atmospheric and climate changes so that preventive measures can be taken before irreversible damage has occurred.

SCIENTISTS FROM THE U.S.S.R. AND EASTERN EUROPE

Question. Dr. Schambra, the changed climate in Eastern Europe and the U.S.S.R. seem to pose an opportunity to the United States and the Fogarty International Center, to greatly expand our scientific exchange programs with those countries. How many scientists from the U.S.S.R. and Eastern Europe are currently included in your programs?

Answer. The Fogarty International Center has several programs which enable Soviet and Eastern European scientists to work with American scientists. For years, their number has been small due to the strict limits on those who were permitted to leave, even for short visits. With the democratization of these countries, many more scientists from these countries are now able to travel abroad, and their first priority is usually to come to the United States to meet and work with their American colleagues.

For years, we have had short-term scientist exchange programs with the U.S.S.R., Poland, Hungary, Bulgaria, Romania and Yugoslavia. Under these programs, FIC and its foreign counterpart institutions support reciprocal visits by U.S. and foreign scientists. In FY 1989, 34 scientists from the U.S.S.R., Poland, Hungary, and Bulgaria visited the U.S. and 21 American scientists visited Eastern European countries. For these countries, our scientist exchange program has been a highly valued opportunity for leading scientists to develop working relationships with U.S. researchers. For other countries, such as Romania, domestic difficulties in recent years have greatly restricted their participation. Now, however, changed domestic conditions in these countries have resulted in greatly expanded participation. Already in FY 1990, requests from Soviet scientists have more than tripled, and have outstripped available FIC resources to the point where we have had to curtail further acceptances. Similarly, Bulgarian officials have asked for expansion of the U.S.-Bulgarian Exchange Program and Czechoslovakian officials have requested the initiation of a U.S.-Czechoslovakia Scientist Exchange Program.

A second mechanism under which Soviet and Eastern European scientists participate in FIC programs is the International Research Fellowship (IRF) Program. The FIC invites an appropriate scientific organization in a country to establish a committee which then may nominate up to six candidates each year to compete with other countries' nominees for IRF awards. These nominees are competitively reviewed by an NIH study section and only those top-ranked candidates receive awards. Previous Eastern European nominees have been highly competitive. In FY 1989, 10 IRF recipients were from Poland, Hungary and Yugoslavia. Both Bulgaria and Czechoslovakia have asked to participate in the IRF program, and other requests are expected.

Regretfully, higher priority commitments preclude FIC from agreeing to these requests to initiate or expand scientific exchange.

Question. What do you estimate the potential to be and what additional funding support would be needed to take advantage of this opportunity?

Answer. I believe one of our greatest opportunities today is to significantly expand international cooperation with Eastern Europe and the Soviet Union on health and biomedical research problems. We have surveyed the interest of NIH scientists in expanding cooperation with their colleagues in these countries and also have heard from a number of biomedical scientists throughout the United States about their interests in the region. Numerous areas for scientific collaboration have been identified, including AIDS, environmental health, cancer, and cardiovascular diseases. Many American scientists believe that Eastern Europe and the Soviet Union offer unusual and important collaborative opportunities. They have also noted that highly competent Soviet and Eastern European biomedical scientists are eager to work directly with U.S. researchers. This could produce benefits for U.S. science. The Soviet Union and the countries of Eastern Europe have expressed a strong interest in participating fully in FIC programs that enable cooperation between their scientists and U.S. scientists. Currently, there is great interest in, and great gains to be achieved from, biomedical research cooperation with these countries.

One area where Americans and Eastern Europeans obviously have a strong common interest is in combatting the spread of AIDS. FIC's programs to train scientists, clinicians, and technical personnel from developing countries in different aspects of AIDS control and epidemiological research could be of very great benefit to Eastern European countries and the Soviet Union. The knowledge we have gained about AIDS will assist them in combatting the threat at an early stage and perhaps prevent a widespread epidemic.

To respond to the potential for U.S.-Eastern European and Soviet cooperation in a variety of health research subjects, FIC has developed a proposal for a 5-year Initiative. This Eastern European Initiative will utilize FIC's existing research and research training mechanisms so that its implementation can proceed rapidly once funds become available. The Initiative also will help train scientists and develop linkages between institutions to form the basis of long-term productive joint research with U.S. biomedical researchers. The estimated cost of this Initiative ranges from $4 million in its first year, to $5 million in its 2nd through 5th years. If the requests for a Director's Discretionary Fund or authority to transfer 1% of NIH appropriations to high-priority areas were approved, items which include recently emerging opportunities of this sort could be funded, at least partially, within the existing budget.

The effect of this Initiative will be to allow FIC to invite all the Eastern European countries and the Soviet Union to participate in the International Research Fellowship Program and the Scientist Exchange Programs. It will also enable considerable research cooperation and training in AIDS, including clinical trials of new drugs and vaccines for the prevention and treatment of AIDS. It would permit as well the NIH Institutes to undertake a broad range of disease-specific collaborative scientific research with centers of excellence in the region. Ultimately, by the 5th year, the Initiative will bring about important long-term scientific, technical, and commercial linkages. We would benefit from this Initiative by being fully informed about the advances in Eastern Europe and the Soviet Union in virology, vaccine development, genetics, and neurosciences.

INTERNATIONAL AIDS ACTIVITIES

Question. About one-third of the FIC budget is devoted to international AIDS activities. What have you accomplished? Are your efforts coordinated with other NIH AIDS programs, and those of the World Health Organization?

Answer. The accomplishments of the FIC international AIDS programs, even after one year of effort, are substantial. A total of 125 individuals from 22 developing countries began training in the first year of the epidemiology AIDS program. The postdoctoral program began training 15 individuals from 10 countries in its first year. In addition, 25 in-country courses were provided for more than 1,000 students in 12 countries through the epidemiology training program. Research conducted by these FIC trainees is addressing some of the most important areas of AIDS investigation, including HIV-2 regulatory proteins, cell-mediated immune responses, mechanisms for killing HIV infected cells, epidemiology of maternal-fetal transmission, and clinical and laboratory features of Kaposi's sarcoma.

FIC's AIDS efforts are well coordinated with other NIH AIDS programs and with those of the WHO. This coordination is achieved through the International Network for AIDS Research and Training established by FIC, working with the Office of AIDS Research and NIAID. FIC also works closely with other parts of the Public Health Service, particularly the Centers for Disease Control and the National AIDS Program Office, and with other Federal agencies, especially the U.S. Agency for International Development.

Special efforts have also been made to coordinate and collaborate with the World Health Organization's Global Programme on AIDS (WHO/GPA) and the Pan American Health Organization (PAHO), WHO's regional office for the Americas. This includes participation by WHO/GPA and PAHO in FIC's International Network for AIDS Research and Training. FIC staff have arranged direct cooperation between WHO/GPA and FIC grantees to establishing a Global HIV/AIDS Network--a telecommunications system linking WHO/GPA with key AIDS programs worldwide. FIC staff have been participating in WHO/GPA Management Committee meetings, in WHO AIDS scientific sessions, and in the organization of the First and Second Pan American Congresses on AIDS.

THE DECADE OF THE BRAIN

Question. This is the decade of the brain. What is the FIC doing in the area of neurology research?

Answer. Recognizing the importance of international efforts in this area, the FIC supports and coordinates a number of international activities in neurology and brain research. The FIC has recently supported a Fogarty Scholar-in-Residence, a world authority on blood flow in the brain, from the University of Lund, Sweden. He is working with scientists from the National Institute of Mental Health on the NIH campus to understand how peptides regulate transmission of electrical signals in the brain. Furthermore, since 1977, the FIC has jointly sponsored, with the National Institute of Neurological Disorders and Stroke (NINDS), an International Neurosciences Fellowship which has provided support for 27 developing country postdoctoral scientists (1 from China in FY 1989) to receive advanced research training in neurosciences in leading U.S. laboratories. These scientists return home to become leaders in neuroscience research and education in their own countries.

Also, in FY 1989, the FIC was responsible for facilitating: (1) the establishment of the Human Frontier Science Program, headquartered in Strasbourg, France. The Japanese government has contributed $20 million to this program, which will support international research in neurosciences and molecular biology including that conducted by U.S. scientists; (2) the negotiation of two agreements in stroke research, one between the NINDS and the Brain Research Institute in Shanghai, China, covers epidemiological studies on stroke; the other is with Italy and will support a study of the causes and treatment of stroke; and (3) the award of 5 research grants (for a total of about $406,000), to foreign scientists supported by NINDS. Finally, the FIC will also arrange for NIH's participation in the International Conference on the Brain in November 1990, sponsored by the Vatican.

Altogether, FIC is quite active in arranging international cooperation in neurological research.

COOPERATION WITH LATIN AMERICAN SCIENTISTS

Question. What special efforts is the FIC making to increase cooperation with Latin American scientists?

Answer. FIC has developed a Latin American Initiative (LAI) in response to: 1) Congressional, Departmental, and Administration interest in increasing U.S.-Latin American cooperation in science and technology; 2) recommendations by the FIC Advisory Board that the FIC should be more active in promoting cooperation with developing countries; and 3) the wishes of U.S., Latin American, and Caribbean scientists to cooperate with one another.

The goals of the LAI are to: increase U.S.-Latin American scientific collaboration; provide U.S. scientists with access to research opportunities in Latin America and the Caribbean; contribute to the development of the Latin American scientific community; and advance U.S. relations with Latin American countries.

With the modest resources heretofore available to begin the Initiative, we have concentrated on efforts to inform the Latin American and U.S. scientific communities of existing opportunities to support research cooperation. We are also providing some funds to enable NIH scientists to visit laboratories in Latin America and the Caribbean for the purpose of developing cooperative scientific projects. And we have worked out new means for NIH laboratories to receive Latin American and Caribbean scientists into their research programs.

Through an expansion of the Initiative, FIC will provide new mechanisms for U.S. and Latin American scientists to undertake collaborative research. In particular, FIC has identified a number of promising research opportunities of mutual interest, including neurological research relevant to the Decade of the Brain, (e.g., neurological and genetic diseases, and cellular and molecular biology of endocrine and neurological functions), maternal and child care (low-birth weight, human lactation, adolescent pregnancy), AIDS, parasitic diseases and their interaction with HIV infection, effects of high altitude physiology on pulmonary and cardiovascular function, and other reactions to environmental and demographic change.

STIPEND AND AWARD LEVELS

Question. Are FIC's stipend and award levels competitive enough to attract good scientists to its programs?

Answer. Good scientists are still attracted to FIC's fellowship programs, although the low stipend levels influence the number of applications received. FIC's International Research Fellows currently receive stipends averaging $20,000 for 1 year, unchanged since 1984. In FY 1989, 10 percent of those awarded fellowships refused the award. One applicant, who was to do research at NIH, stated in his response letter that the stipend was insufficient for him to support a family in the Washington, D.C. area and therefore he could not accept the award. U.S. sponsors are constantly stating that the stipend is too low and imposes a hardship on awardees.

The Senior International Fellowship (SIF), awarded to mid-career U.S. scientists, currently provides a stipend level of $15,000 per year and a foreign living allowance of $15,000, also unchanged since 1984. Comments made by former Senior International Fellows and other scientists interested in applying to the SIF Program indicate that this award is insufficient to live abroad, particularly in Europe where most of the U.S. awardees conduct advanced research. Clearly, we are losing good scientists to this important program as well. A major benefit of this program is that it gives American scientists an opportunity to have direct access to European technology and apply this knowledge at U.S. institutions.

Traditionally, NIH policy has placed priority on maintaining the number of grants and awards. FIC has complied with this policy and sustained the number of awards rather than increase stipends.

RESEARCH MANAGEMENT AND SUPPORT

Question. I see that about 38 percent of the FIC budget is "Research Management and Support." What activities are covered by this category?

Answer. The Research Management and Support (RMS) category includes a number of essential FIC research programs and services to the NIH scientific community and other agencies in addition to staff salaries and overhead costs.

RMS includes funding for FIC's International Research Coordination and Scientific Exchanges Program which supports exchanges of scientists under bilateral agreements. Also included are FIC's Latin American and Eastern European Initiatives, and the International Advanced Studies Program in which FIC Scholars-in-Residence conduct in-depth studies and analyses of such problems as the applications of molecular genetics to inherited nervous disorders, and the role of membrane barriers in the control of cellular functions.

RMS funds are also used to provide essential support services to the international scientific programs of NIH and other federal agencies. This includes giving administrative support to the approximately 2,400 foreign scientists in the NIH Visiting Program; providing coordination and liaison for the NIH Institutes with foreign embassies and Ministries of Health and with U.S. embassies and the Department of State for various foreign policy initiatives; and providing health attaches posted in the U.S. Embassy in India and the U.S. Mission in Geneva.

INTERNATIONAL RESEARCH AND AWARDS

Question. The Committee supported funding for the international research and awards program because it provides an avenue for obtaining valuable information about advanced biotechnology programs in advanced foreign countries. What important biomedical and biotechnology information from foreign countries was made available to the United States under your program last year?

Answer. U.S. scientists in the Senior International Fellowship Program benefitted considerably from information obtained last year in foreign laboratories including the area of biotechnology. For example, a scientist from the University of Pennsylvania has been working with an internationally known researcher at the University of Oxford, England, using molecular biology techniques to study the mechanisms of differentiation of bone marrow stromal cells into mature osteoblasts (bone cells). Their work should lead to progress in healing bone fractures and prevention of osteoporosis.

A scientist from the University of Kentucky is conducting research in neurobiology on the mechanisms of repair of the brain after trauma. The research is being conducted at a leading laboratory of the Institute of Genetics, at the University of Cologne in the Federal Republic of Germany. The possible benefits for those with brain injury after accidents is enormous.

A scientist from the Pennsylvania State University is examining whether neuropeptide Y inhibits the vasoconstriction associated with congestive heart failure. His findings could provide new clinical treatments for patients with heart disease. His collaborator, from Lausanne, Switzerland, is internationally known for research on vasomotor regulatory mechanisms in hypertension. This collaboration, uniting two internationally recognized scientists, will accelerate research in this important area in the United States.

A scientist from the University of Oklahoma will study prognostic indicators (e.g., nuclear DNA and oncogene products) in patients with central nervous system cancer. The collaborating laboratory at the University of Leyden in The Netherlands is one of the few places in the world where such a study can be conducted. Ultimately, through this collaboration, this new research methodology will be performed in the United States.

A scientist from the Medical College of Wisconsin will investigate the role of complex carbohydrates in the pathobiology of HIV. The collaborating laboratory at the University of Rome, Italy, provides an excellent opportunity to study this important aspect of the structure of the AIDS virus and apply this knowledge to research on the AIDS epidemic.

A scientist from the University of California, Davis collaborated with colleagues at Oxford University, England to apply recombinant DNA technology to Baculoviruses (insect virus). The research conducted by this investigator has resulted in the development of a prototype for a genetically engineered viral insecticide. The special molecular biology skills learned during this sabbatical will be taught to his colleagues and students and applied to health problems in the United States.

INTERNATIONAL NETWORK FOR AIDS RESEARCH AND TRAINING

Question. During the past decade, AIDS has spread rapidly across international boundaries. FIC continues to support international research training programs on AIDS in order to develop a cadre of scientists able to conduct collaborative research and clinical trials. To further this work, FIC recently collaborated with NIAID to establish an International Network for AIDS Research and Training. Please describe the purpose of the Network and its benefits to AIDS research worldwide.

Answer. The purpose of the International Network for AIDS Research and Training is to coordinate AIDS research efforts worldwide, avoid duplication, identify research and training needs, and better respond to emerging problems. It also will create a sense of unity and purpose for those battling AIDS worldwide. The network was established by FIC, in cooperation with NIAID and the NIH Office of AIDS Research and the WHO/GPA, and represents an informal network of AIDS investigators and program officials. It includes approximately 100 individuals who represent some of the most prominent AIDS researchers at the NIH, CDC, U.S. academic institutions, USAID, WHO/GPA, and PAHO.

Two major meetings of the network have been held, one at the NIH, January 30-31, 1989 and the other at the University of California, Berkeley, September 14-15, 1989. The network benefits AIDS research worldwide in a number of ways. The January 1989 meeting, for example, provided an opportunity for participants to brief each other on their respective programs and to discuss such issues as approaches to research training in developing countries, and experiences and requirements for research training and long-term collaboration. The September 1989 meeting included a detailed discussion of HIV/AIDS surveillance and epidemiology.

Examples of the network's achievements are: more rapid dissemination of information between WHO/GPA, PAHO, NIH, and CDC program participants; increased dialogue between FIC- and NIAID-funded international AIDS programs directors and investigators; increased opportunities for NIH-funded researchers to participate as advisors to WHO/GPA; increased participation by FIC grantees in NIAID's International Collaboration in AIDS Research (ICAR) program and in the recently established grants program of the World AIDS Foundation.

INTERNATIONAL RESEARCH ACTIVITIES

Question. The International Research Activities section of the FIC provides funding for the FIC's extramural research programs. In FY 1991, the budget request for International Research Activities is $5,563,000 reflecting a decrease of $45,000 from the FY 1990 appropriation. What is the reason for this $45,000 decrease?

Answer. In order to provide our share of the tap for the new Agency for Health Care Policy and Research, pursuant to P.L. 101-239, FIC reduced allocations to its extramural programs by $45,000. The remainder of our tap (approximately $64,000), will come from FIC's Research Management and Support portion of the budget.

Question. Is the requested amount enough to fund the projected 189 FIC awards?

Answer. We expect that the requested amount will fund close to 189 new and non-competing continuation awards. However, we will not be able to fund short-term supplements for International Research Fellows who request a few month's extension to their stay as the United States.

Question. If more resources were available could the FIC make awards to additional, qualified researchers?

Answer. Yes. Despite the low stipend levels, FIC still receives enough applications of good quality to justify additional awards if more resources were available. We could fund an additional 20 or 25 International Research Fellowships, 10 to 12 additional Senior International Fellowships, and 3 to 5 additional Scholars-in-Residence. Of course, the number of applications of high scientific merit would be even larger if all Eastern European countries and the Soviet Union were able to participate in these programs.

Question. What other international programs under the FIC would you consider to require increased funding?

Answer. One of the greatest opportunities today lies in expanding fruitful cooperation with Eastern European and Soviet scientists. The FIC has developed a special Initiative to take advantage of these opportunities but would require increased funding.

I've described our Latin American Initiative which we have started with approximately $50,000 in FY 1990 and for which we are requesting $100,000 in FY 1991. However, to have a meaningful program and take advantage of the many mutual scientific interests and opportunities will require an expanded effort. To fully implement this Initiative would require additional funding, and would be expended in the following manner:

- o Additional fellowships for Latin American scientists to conduct research and receive research training in U.S. laboratories;
- o Supplements to domestic grants to increase U.S. scientists' ability to engage in cooperative research activities with Latin American scientists;

- Short-term scientist exchanges involving U.S. and Latin American scientists to engage in collaborative research and training; and

- Exploratory workshops to identify areas of mutual interest and to develop plans for future research cooperation.

Our international AIDS programs, currently funded at only 70 percent of the approved amount, requires increased funding to fully support FIC's 14 training grants; to extend them to other countries where the AIDS epidemic is rapidly expanding; and to provide necessary support for FIC's International Network for AIDS Research and Training which coordinates FIC, NIAID, and other NIH AIDS activities with the World Health Organization.

MEDICAL RESEARCH LABORATORIES IN DEVELOPING COUNTRIES

Question. An important priority of the FIC's international research efforts is the establishment of medical research laboratories in developing countries. One of the most successful efforts in the Biomedical Research Institute for Clinical Infectious Diseases (BRICID) in Cairo, Egypt. Please discuss the success of this institute and current efforts to establish medical research laboratories in other developing countries.

Answer. The Biomedical Research Institute for Infectious Diseases (BRICID) was established in 1965 in Cairo, Egypt, as part of the Egyptian Ministry of Health. Major financial support has been from the U.S. Agency for International Development (USAID), but other substantial funds came from the Rockefeller Foundation, the Clark Foundation, and WHO. A major factor in the success of the laboratory has been the collaboration of Egyptian scientists with both NIH intramural and NIH-supported extramural American scientists. This interaction led not only to scientific advances by the laboratory, but also to an effective management structure to administer a medical scientific institute in a developing country so that its scientists can work productively. This has required a managerial and administrative superstructure, the establishment of laboratory facilities, the development of human resources, including maintenance personnel, and the development of a budget office accounting system.

Since 1965, BRICID laboratory staff published, in collaboration with their American colleagues, more than 40 scientific papers in Western medical journals. The laboratory has served as a training ground for young Egyptian scientists. It has granted 4 Ph.D. degrees, and 5 M.A. degrees, and has trained 31 technicians in advanced techniques in epidemiology, statistics, bacteriology, immunochemistry, and immunology. About 4 years ago, the laboratory's first director retired and one of the 4 original Ph.D. recipients has taken his place. Thus, the institution has been successful in developing personnel for its own continuity.

BRICID's scientific contributions include: defining criteria to diagnose rheumatic fever in children in developing countries; implementation of methods of prevention of rheumatic fever in Egypt; clinical trials of a successful meningitis vaccine developed by

American scientists; and successful trials on the use of drugs to prevent the transmission of schistosomiasis among Egyptians living in the Nile Delta.

Current work includes an international effort to develop immunological approaches to the control of schistosomiasis, and clinical and bacteriologic efforts to quickly identify infants and young children with lower respiratory tract infections. Early diagnosis is essential if these young children are to be treated successfully. These infections are frequently fatal and are very common in developing countries. U.S. scientists continue to collaborate in these efforts.

The FIC staff continues to participate in the group of PHS and USAID scientists that advance the direction of BRICID.

The Fogarty International Center has also helped coordinate U.S. Public Health Service efforts to develop laboratories in other countries. These efforts include: an AIDS project in Kinshasa, Zaire; the vector-borne diseases laboratory in Cairo, Egypt; and a vaccine laboratory in New Delhi, India. The FIC also has made a major commitment to train junior scientists from developing countries who return home to staff medical research laboratories. A recent evaluation of the Fogarty International Research Fellowship program demonstrated that the vast majority of these fellows do return to their home countries and work in biomedical research laboratories and medical schools. Many have been instrumental in developing new research centers in their home countries. Hence, this program introduces the latest scientific techniques to laboratories throughout the developing world. Importantly, these fellows maintain scientific ties with their U.S. scientific mentors and are active publishers with them. Thus, ongoing and future collaborative work between them continually and increasingly strengthens the laboratories in those developing countries.

INTERNATIONAL NURSING RESEARCH INITIATIVE

Question. In light of the continuing worldwide nursing crisis, the FIC continues to expand its efforts internationally to recruit additional nurses into research and research training. Please provide us with an update on the progress of the International Fellowship Program for postdoctoral nurses.

Answer. Following discussions between the Directors of the FIC and the National Center for Nursing Research (NCNR), the FIC developed an approach for recruiting more nurses into research and research training through its various individual fellowship and AIDS training programs.

We are particularly pleased that nurses are participating in FIC's international AIDS training programs. In fact, nurses represented 4 percent of the program's first year trainees. Included were three nurses from Malawi, who participated in the summer training program at the Johns Hopkins University. Also, the FIC-supported training program at Case Western Reserve University has recruited a senior nurse to coordinate its nurse training efforts in Uganda. An in-country training course for nurses is planned for this year in Uganda. And a nurse from Uganda was enrolled in a short-term training course at Case Western Reserve University. A one-week course on the nursing aspects of HIV and AIDS will be given this summer in Honduras by the FIC-supported program at the University of Miami. FIC and NCNR are discussing ways of increasing nurse participation in the AIDS training program as a means to further encourage nurses to enter research.

We have also worked with NCNR to develop an announcement describing individual research opportunities for foreign postdoctoral nurse researchers through NIH programs. The announcement was distributed widely by a member of the FIC Advisory Board whom FIC supported to participate in the recent meeting of the International Council of Nurses in Seoul, Korea, and in the Congress of the International Honor Society of Nursing in Taipei, Taiwan. Although no applications from nurses were received last year for our individual fellowship programs, the FIC expects to receive more applications in future years as a result of this announcement. The FIC has received a number of inquiries from nurses concerning the fellowship program, and has scheduled additional meetings with the NCNR to explore strategies for attracting nurse participants.

In addition, staff from FIC and NCNR have begun discussions on how to develop an NIH visiting program for foreign nurses similar to that which exists for foreign physicians and scientists at the NIH.

FIC APPROPRIATIONS

Question. Since 1981, the FIC has received the smallest increase in appropriations of any of NIH's components. During this 10 year period the FIC's appropriation increased 45 percent compared to 90 percent for all of NIH. In terms of constant dollars the FIC's funding actually decreased by 13 percent compared to NIH's increase of 14 percent during this same period. Dr. Schambra, why do you think the FIC has received the smallest increase in appropriation since 1981?

Answer. There are several reasons why the FIC has received the smallest increase of any of NIH's components in its non-AIDS programs since 1981. First, most other NIH components support and conduct research on specific diseases that threaten the health of people in the United States and around the world. Because public advocacy groups and the Congress place a high priority on the prevention and treatment of specific diseases, budgets of NIH components engaged in direct research on these diseases have had regular and sizeable increases over the years. FIC's international programs, however, because they must cover every scientific area of relevance to NIH's mission including basic biomedical, clinical, and behavioral research, have not developed a strong disease-oriented constituency of its own.

Second, a large proportion of the FIC budget must be carried in the "Research Management and Support" category, but for FIC that category increasingly supports important scientific activities such as international studies, consultations and research strategy meetings, and scientific exchanges and special initiatives with Latin America and Eastern Europe. The FIC has also absorbed an increased workload in its international coordination and liaison work (due to increases in bilateral agreements and scientific exchanges), and has supported the growth in the NIH foreign visiting scientists' programs. Other NIH components have a sizeable proportion of their budget in research grants, which traditionally receives higher increases in the adjusted base. FIC's fellowship programs and scientific programs in the RMS category have not attracted similar increases.

Third, throughout most of the 1980s, Administration and Congressional interest in the FIC focused not on FIC programs per se, but rather on the support for and problems of the Gorgas Memorial Institute and the Gorgas Memorial Laboratory in Panama. As of FY 1989, at Congress' direction, responsibility for any further support for Gorgas was transferred to NIAID. This has allowed the focus to shift to other aspects of FIC's programs and plans which, hopefully, will receive the support they merit.

Question. Are you satisfied that the overall FIC program is receiving the fiscal attention that it deserves and do you have any additional recommendations for the committee as to how the FIC program could be improved?

Answer. I believe FIC programs in the past have not received the fiscal attention that they deserve. However, the world has changed and is changing in ways which will increasingly emphasize the necessity and benefits of international scientific cooperation. The complexity, pace and cost of modern science mandates that American scientists collaborate with the best of their foreign colleagues and take advantage of new scientific opportunities such as those opening up in Eastern Europe and the Soviet Union. The greater ease and frequency of global travel means increasing exposure to and spread of disease. Higher population densities and the growth of mega-cities raise the likelihood of the emergence of new diseases such as AIDS. And solutions to health problems are increasingly likely to be found by working with foreign scientists and in foreign countries.

There are several ways FIC programs could be improved. Stipend increases for the International Research Fellowships and the Senior International Fellowships could generate more interest and thereby improve the overall effectiveness of these programs. Additionally, two special Initiatives, one focused on expanding cooperation with Eastern European and Soviet biomedical scientists, and the other with Latin American and Caribbean scientists, would yield significant benefits to the people of their regions and the United States. Finally, expansion of our AIDS programs would enhance research efforts to combat this dread disease.

Question. You have indicated that the initiative to enhance cooperation in biomedical research with Latin America is a high priority. How much money have you budgeted for this initiative?

Answer. In the Administration's request for FY 1991, the FIC would devote $100,000 to the Initiative. These funds will be used to support short-term consultations between NIH and Latin America scientists to develop new research collaboration in priority areas of special interest and to identify qualified scientists and institutions for participation in NIH research programs.

Question. What would be needed to fully fund this effort?

Answer. FIC's Latin American Initiative would require $2.2 million to be fully implemented.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

EASTERN EUROPE AND THE SOVIET UNION

Question. Dr. Schambra, recent changes in the political character in the nations of Eastern Europe and the Soviet Union appear to offer great opportunities for scientific collaboration. This could contribute significantly to enhancing the quality and stability of life both in the United States and in these changing nations. What action has the Fogarty International Center taken to respond to these historic opportunities?

Answer. These are, indeed, historic opportunities, and recognizing that fact, we have surveyed the interest of NIH scientists in expanding cooperation with their colleagues in Eastern Europe and the Soviet Union. We have also heard from many biomedical scientists throughout the United States about their interests in the region. Numerous areas for scientific collaboration have been identified, including influenza and other virus infections, AIDS, environmental health, cancer, and cardiovascular diseases. Many American scientists believe that Eastern Europe and the Soviet Union offer unusual and important collaborative opportunities. They have also noted that highly competent Soviet and Eastern European biomedical scientists are eager to work directly with U.S. researchers. This could produce benefits for U.S. science The Soviet Union and the countries of Eastern Europe have expressed a strong interest in participating fully in FIC programs that enable cooperation between their scientists and U.S. scientists. Currently, there is great interest in, and great gains to be achieved from, biomedical research cooperation with these countries.

One area where Americans and Eastern Europeans obviously have a strong common interest is in combatting the spread of AIDS. FIC's programs to train scientists, clinicians, and technical personnel from developing countries in different aspects of AIDS control and epidemiological research could be of very great benefit if extended to Eastern European countries and the Soviet Union. The knowledge we have gained about AIDS will assist them in combatting the threat at an early stage and perhaps prevent a widespread epidemic.

To respond to the potential for U.S.-Eastern European cooperation in a variety of health research subjects, FIC has developed a proposal for a 5-year Initiative. This Eastern European Initiative which could also be expanded to include the Soviet Union, will utilize FIC's existing research and research training mechanisms so that its implementation can proceed rapidly once funds become available. The Initiative also will help train scientists and develop linkages between institutions to form the basis of long-term productive joint research with U.S. biomedical researchers.

The effect of this Initiative will be to allow FIC to invite all the Eastern European countries and the Soviet Union to participate in the International Research Fellowship Program and the Scientist Exchange Programs. It will also enable considerable research cooperation and training in AIDS, including clinical trials of new drugs and vaccines for the prevention and treatment of AIDS. It would permit as well the NIH Institutes to undertake a broad range of disease-specific collaborative scientific research with centers of excellence in the region. Ultimately, by the 5th year, the Initiative will bring about important long-term scientific, technical, and commercial linkages. We would benefit from this Initiative by being fully informed about the advances in Eastern Europe and the Soviet Union in virology, vaccine development, genetics, and neurosciences.

Question. Does the budget for FY 1991 include additional funding to support expanded fellowships and exchanges with Eastern Bloc nations?

Answer. The FIC budget request for FY 1991 includes an additional $50,000 to support exchanges with Eastern Europe and the Soviet Union.

Question. In your professional judgment, how much would be necessary to adequately respond to the expanded opportunities?

Answer. The FIC has developed plans for a 5-year Eastern European Initiative that ranges in cost from $4 million for the first year to $5 million in each of the following years. The essential elements of the first year of this Initiative are:

- Research grants for U.S. scientists to conduct collaborative research with Eastern European scientists. American scientists who already have research grant support from NIH (and therefore already have an active, funded domestic research program) will be invited to apply for these grants through the regular NIH grants review process. These grants will cover additional costs of conducting research in the American scientist's laboratory in cooperation with an Eastern European scientist. They will provide for the purchase of supplies and equipment needed by the Eastern European scientific collaborators in those instances where this would expedite the progress of the research. These grants would also pay for scientific exchanges so that the investigators in both countries can work together. Topics covered by these research grants would include cancer, cardiovascular disease, influenza and virus diseases, neurological disorders, environmental health, aging, and other scientific areas of high mutual priority.

- Training grants in U.S. institutions for Eastern European scientists and health professionals who support these research efforts. These grants would focus on providing training for Eastern European scientists and health professionals concerned about scientific and medical aspects of AIDS. These grants could supplement existing international AIDS training grants already awarded by the Fogarty International Center to ten U.S. universities

(Harvard, Cornell, Case Western Reserve, Emory, Johns Hopkins, Miami, Washington, Tulane, University of California at Berkeley, and the University of California, Los Angeles). These are active programs involving a large number of foreign students from many countries and would be able to receive additional trainees in a short period of time.

o Research fellowships to support Eastern European scientists in U.S. biomedical research laboratories. These fellowships would be offered through the Fogarty International Center's International Research Fellowship Program which supports young scientists for one to two years to train and conduct research in U.S. biomedical research laboratories. These additional funds would enable FIC to respond to requests from Bulgaria and Czechoslovakia to participate in this program and to expand this program in other Eastern European countries. Training would be in any biomedical research area that was of mutual interest to a U.S. sponsor and the foreign fellow.

o Short-term exchange research consultations between U.S. and Eastern European scientists. The support would be based on brief peer-reviewed applications from Eastern European and American scientists and would be for the purpose of supporting travel and per diem for scientists to develop collaborative research consultations in each other's countries for periods up to 6 months. The purpose of these consultations is to enable the scientists to develop plans for longer-term collaborations. The subject areas could include all fields of biomedical science of mutual interest.

o Scientific workshops. Up to 10 workshops would be designed to bring together individuals with common scientific interests to exchange information, develop linkages and define areas of promising scientific collaboration between individuals and groups in both countries. The subject areas covered would be broad, but would include such topics as AIDS, human genome research, aging, environmental health, brain research, and cancer.

STIPEND FOR INTERNATIONAL RESEARCH FELLOWS

Question. Dr. Schambra, I note that the stipend for the International Research Fellowship program is 30 percent below the average stipend of other NIH fellowship programs. What is the reason for this disparity?

Answer. The International Research Fellowship (IRF) stipend, unchanged since 1984 at an average level of $20,000, has lagged behind other fellowship stipends for a number of reasons. First, in compliance with the NIH policy to maintain the number of awards, FIC has held the number of awards at a constant level. Second, because we receive multiple nominations from 55 participating countries, we believe that the number of fellowships cannot be reduced below 90 and still maintain an active program.

Question. Have you considered raising the stipends to more adequately reflect the average stipend at the NIH?

Answer. Yes, for a number of years the FIC has included a stipend increase for the IRF Program in our professional judgment budget requests, but appropriations received did not include sufficient funds to cover the cost. Due to the competing demands of our other program activities, including the need to maintain the IRF Program at no fewer than 90 awards, we were not able to cover the stipend increase within available resources.

Question How much would be required to raise the stipend and maintain the same level of fellowships?

Answer. $966,000 would be required to raise the stipend level for the IRF program to an average of $27,000 and maintain the same number of fellowships.

CLINICAL TRIALS

Senator **Harkin**. Dr. Gorden, you are midway through a 10-year clinical trial that includes approximately 1,400 people, testing whether or not very intense management of blood sugar levels can have positive results in terms of the progression of the disease.

I understand this trial costs about $17 million a year, and it is scheduled to run through, at least until 1994.

Do you believe it is still necessary to run it until 1994, or could we expect earlier results which would permit us to conclude the trial earlier than that?

Dr. **Gorden**. We are certainly continuing to monitor the study very carefully. I do not anticipate that we will be able to conclude it before the date that you said. The study is designed to test two different types of insulin treatment, a more conventional type and a very intensive type of insulin treatment.

We clearly have met the initial objectives of this study, that is, to separate the glucose or sugar parameters that were set for the study. That has happened. The recruitment has gone well. Both limbs of the study are fully recruited, and there is a major effort to see whether either of these therapeutic modalities will have a positive outcome on the complications, that is the eye, nerve and kidney complications of the disease.

It is really a major effort at determining what we can do now and whether it really is effective. So that is the reason I think we will have to see this through until we can actually get an answer to that.

DIABETES

Senator **Harkin**. You talked in your statement a little bit about type 1 and type 2. What prospect is there for a cure for type 1 in diabetes?

Dr. **Gorden**. There has been a remarkable degree of progress in this area, in the sense that we have described the type of disease this is. It is an immunologic attack against a small population of cells that make insulin.

We have discovered a major susceptibility gene, a particular form of a gene that renders the individual susceptible. In addition to that gene which is necessary, something else has to trigger the ultimate disease.

That is a very intense area of research. We have proceeded to the point where we can actually identify approximately four markers for this disease before the disease becomes manifest. This is the form of diabetes that occurs in children.

It used to be that a child would come to the hospital very sick, in what is called diabetic ketoacidosis, and it was assumed that the child was well, playing and just fine 2 days before, so the disease must have happened within 2 days. That is not true.

The fact is that we now know that the disease has been going for several years, 4, 5, possibly 10 years, and we now have some very precise markers. We are going to have a conference next month in which we address the question of whether or not we have a sufficient amount of data to warrant treatment of those children before they manifest the disease.

I believe we will find an important remedy for the disease before we actually find a cure, if you mean by cure, something that would totally eradicate the process.

I think that there is a great deal of progress being made in that particular area.

INFANT MORTALITY

Senator **Harkin**. Dr. Alexander, since the hearings last year our ranking in infant mortality has dropped from 18th to 22d, even though you had a different spin on the terms that it has been reduced, evidently the other countries have reduced it more, and we have now fallen from 18th to 22d.

One of the major causes, as I understand it, is low birth weight. There has been no improvement in the low birth weight portion of the infant mortality rate.

Can you expand on that a little bit? I hear this wherever I go, about our high infant mortality rate and how bad we are in the world community. What could we do to collapse that in a very short frame of time?

Dr. **Alexander**. Part of the change you refer to in the international ranking resulted from changes in the standards of what qualified as a country, and number of births was one such standard. Also whether we are 20th or 22d, depends on whether the United Kingdom is considered as one country or three.

Our ranking is somewhere in that range. The change since last year has really been negligible in terms of that ranking. What is important is that the infant mortality rate continues to decline, although the rate of decline has slowed, and our incidence of low birth weight has not improved. It remains around 6.9 percent.

Many of the gains that we have achieved in infant mortality have occurred in the first 28 days of life. We have achieved those gains largely by applying improved technology to newborn infant care and particularly for low birth weight infants.

A low birthweight baby has a better chance of surviving in the United States than anywhere else. Our problem is that we produce proportionately more of them. We have an extensive research program trying to find out why some babies are born too soon or too small.

Some reasons we already know, for example, the relationship between smoking and low birth weight has been established. Of all the things that we know how to do to prevent low birth weight, avoiding smoking in pregnancy is the leading one.

The NICHD has a number of programs that have been designed to try to keep women from smoking or to have them stop smoking during pregnancy. One program in conjunction with the American College of Obstetricians and Gynecologists that is currently being implemented in our prevention research program is the smoking trial of pregnancy, or STOP for short.

STOP is an office-based clinical trial designed for use in obstetricians' offices so that when a pregnant woman comes in and is observed to be a smoker, the obstetrician and the office nurse can work with this patient in applying the methodology outlined in STOP to encourage her to reduce her smoking or ideally eliminate it.

We have produced some very attractive materials for this program. We hope that with an intervention like this, designed to be applied from the physician's office, with continued followup from the office nurse, we can make a difference in the incidence of smoking in pregnancy and thus reduce the incidence of low birth weight.

Senator **Harkin**. I hope you continue to highlight that in your testimony and other things that you do. We all have bits and pieces of this, but it seems that in terms of child health, you can again focus a lot on preventative health education.

I toured a neonatal care unit here not too long ago and the technology is mindboggling, what they do with these young babies and how they care for them. The price is also mindboggling.

Dr. **Alexander**. That is right.

Senator **Harkin**. Cost, I should say. You cannot force people, but if you can get these people beforehand, and give them some kind of incentives for stopping smoking. I did not know that it is the chief cause of low birth weight babies.

Dr. **Alexander**. That we know.

Senator **Harkin**. We ought to really put major efforts in that area. If we can effect a certain small percentage of those people who otherwise might have low birth weight babies, that it is going to save money.

Dr. **Alexander**. We believe it can make a difference. I would be glad to share some of those materials that we have developed with you and your staff.

CONTRACEPTIVE DEVELOPMENT

Senator **Harkin**. One thing I wanted to cover was contraceptive development, and you touched on it in your statement. I understand that an estimated 52 percent of pregnancies are unintended, and that one-half of these unintended pregnancies result in abortion, approximately 1.5 million abortions per year.

Another statistic that has been reported to me is that approximately one-half of these abortions result from cases where contraceptive devices were used but failed.

Does this situation suggest the need for new and additional contraceptive research?

Dr. **Alexander**. Mr. Chairman, we believe the data speak for themselves, and suggest the need for more extensive contraceptive development research. The figures that you cite came from the National Survey of Family Growth from 1985 to 1987, which was partly supported by our Institute.

A recent report just released last week by a committee from the Institute of Medicine and the National Academy of Sciences on "Contraceptive Development: Opportunities and Obstacles," reached the same conclusions. This report outlined that in this country, there is a lack of sufficiently effective contraceptives as well as an inadequate variety of contraceptive methods. Thus, there is a need to develop new and improved contraceptive methods and to make them available to the public.

Of special concern is the fact that of the people who have resorted to abortion, one-half of those have done so because of contraceptive failure. We believe that we need to develop methods that are more effective.

We have a number of new methods under development in our contraceptive research program. These range from skin patches for delivery of contraceptive hormones, to implants and injectable methods, to other totally new approaches to contraception that are being developed at the present time.

Some of these are a year or two away from application, others are much farther, but it is important that we continue to work on them all.

MALE CONTRACEPTIVES

Senator **Harkin**. Are we doing adequate research in this or have we shunted this aside? Either you stated it in your testimony or I read it in your testimony, about the perhaps reversible male contraceptive that blocks the——

Dr. **Alexander**. It is a luteinizing hormone releasing hormone, LHRH. It is a very complicated name——

Senator **Harkin**. I cannot remember that, but you know what I am talking about.

Dr. **Alexander**. We have been experimenting with these types of substances for a number of years, and we have modified their chemical structure, and have come up with analogs that are more effective in reducing sperm production while at the same time eliminating the histamine-releasing problems when they are injected that can cause itching, burning, and other adverse reactions.

We now have products we feel are free of these particular side effects. We also have developed long-acting injectable testosterone replacement that would have to be given concomitantly with this particular analog.

This substance is in clinical trials which will be expanded in the course of the next year. It does offer the promise of reversible and highly effective male contraception.

DOLLARS FOR CONTRACEPTIVE RESEARCH

Senator **Harkin**. How much money are we putting in every year toward contraceptive research? Do you have any idea? Could you supply it to us? Do you have any offhand ideas?

Dr. **Alexander**. In the past 6 years, the amount in the contraceptive development applied research program has been ranging between $8 million and $8.5 million a year. If you add in the basic research component and behavioral studies, the entire contraceptive program totals around $18 million.

Senator **Harkin**. What are other countries doing?

Dr. **Alexander**. The United States has one of the larger Government-supported programs. Some of the other countries contribute to the World Health Organization combined effort. India and China also invest substantially in contraceptive development research.

CONTRACEPTIVE RESEARCH BY PHARMACEUTICAL COMPANIES

Senator **Harkin**. Why are not pharmaceutical companies in this country engaged in that research?

Dr. **Alexander**. The pharmaceutical industry really led the way back in the 1950's and the 1960's in this area, but in the 1970's and 1980's, has almost completely dropped this line of research.

At the present time, only one pharmaceutical company, Johnson & Johnson, through its Ortho Division, is actively engaged in contraceptive development research. This has occurred for a number of reasons. It is partly due to the prohibitive cost of new drug development, and partly to the extensive testing that is required by the Food and Drug Administration for contraceptive products because they are designed to be given to healthy people over a long period of time.

But probably the most important factor in all of this has been the problem of product liability. Pharmaceutical manufacturers are liable over a long period of time for any claims against a contraceptive drug or device.

The decisions of courts in these suits do not always follow science or logic, and large verdicts have been rendered against pharmaceutical companies in the face of clear evidence that the particular device did not cause the defect.

This has scared pharmaceutical companies out of the business, and unless we are able to provide some sort of protection for them from these suits, they are not likely to return.

The same product liability problem has afflicted our own contraceptive development program. Several of the devices we have developed have not been able to proceed on to clinical testing because product liability insurance has not been available at any price. So these products basically have been stopped in their development.

We have been able to overcome this in some instances, only by going to universities for the clinical testing where the universities have their own liability insurance coverage or some way of indemnification for the particular contractor.

So it has been a problem with our contraceptive development program as well as for the pharmaceutical industry.

Senator **Harkin**. You say you cannot even get liability insurance?

Dr. **Alexander**. That is correct.

Senator **Harkin**. And you say we only have one now doing active research and that is Johnson & Johnson?

Dr. **Alexander**. That is correct.

Senator **Harkin**. What area of contraception are they doing the research in?

Dr. **Alexander**. They are doing research in modification of existing hormones, trying to find agents that have a smaller degree of effect on blood lipids and cardiovascular effects, and also on other devices and other injectables.

Senator **Harkin**. It seems to me that one of the major answers to abortion is improved contraception.

Dr. **Alexander**. We agree and that is one of the reasons we have pushed this program as extensively as we have. For the past 3 years we have had a special initiative in contraceptive development, trying to move these products through the pipeline as quickly as possible, as well as to invest in the basic research that will give us new leads for totally different contraceptive approaches.

We have identified some of those in our basic research program and continue to try to promote them.

PUBLIC AWARENESS

Senator **Harkin**. Thank you very much, Dr. Alexander.

Dr. Rall, the causative agents that your Institute studies tend to be a little bit more controversial than some of the other studies in the other Institutes.

Dr. **Rall**. I think that is a fair statement.

Senator **Harkin**. Fair statement, right. In view of this, I am wondering what your philosophy is in the fact that your Institute studies chemicals which while they may cause illnesses also have a very positive benefit. They may have a benefit some place but may have a detrimental effect some place else.

What is your philosophy, the Institute's philosophy, in being aggressive in bringing to the attention of all the appropriate officials, the public health concerns that you have with chemicals on the market?

As an example, if you discovered that one of our favorite soft drinks had very serious negative health implications, how would you handle that?

Dr. **Rall**. Sometimes I envy those people who work against viruses. The only way one can handle that is to make the scientific data as good as possible. Have it effectively peer reviewed by impartial, highly competent, outside scientists and then do an adequate job of publicizing those facts.

We put out the so-called annual report on carcinogens which was requested by Congress back in 1978, to list all of those chemicals which are known to be carcinogens or may reasonably be anticipated to be carcinogens.

The first category is easy. They are those that are known to be carcinogens, proven by human studies. The second category is much more speculative. We have established strict rules as to what is and what is not.

We have a series of committees that make this judgment. We use only data that is peer reviewed. We were sued, as some of you know, last summer about the inclusion of one chemical in this list, as reasonably anticipated to be, by what turned out to be most of the chemical industry. We won, I am happy to say, and that now is in that annual report of carcinogens.

It is sometimes very difficult and I think you have pinpointed one of our problems. This does not diminish our sense that we need to continue to do this sort of study. Epidemiological studies tend not to be very sensitive. They can miss small changes which still might have important public health implications.

We think to get these compounds studied very early is very important, so that you know as soon as possible the extent to which they may or may not cause harm.

I am worried, as you probably know, about pesticides. In recent surveys, 3 or 4 years ago, which is the latest we have, the vast majority of the pesticides have not been adequately studied in animal experiments. We are doing our best to study them. We are limited to about 12 new compound starts a year because testing chemicals in laboratory animals and doing it right and doing it carefully is quite expensive.

CENTER FOR HEALTH EFFECTS OF AGRICULTURAL CHEMICALS

Senator **Harkin**. Dr. Rall, as you know, the committee and I personally are very interested in your establishing a research center for the health effects of agriculture chemicals. I just cannot overemphasize the concern that farmers and others have on what has happened to them because of chemicals.

I have a lot of anecdotal evidence reported to me by farmers and people in the rural areas around Iowa about negative health aspects of agricultural chemicals. People in rural areas are getting more concerned because of the high incidence of cancer, respiratory ailments, and things like that.

What is the progress for establishing a center to look at the health effects of agricultural chemicals?

Dr. **Rall**. It looks very promising that we will be able to fund it in this fiscal year. I quite agree, I think perhaps some of us who lived in the city had not really realized. One problem that I think is worth looking into is the fact that city dwellers, although we have paint in the houses, tend never to deal now with leaded gasoline, but much of the farm equipment runs on leaded gasoline.

So here is a source of lead exposure that in the city is essentially gone, but is still prevalent on the farm. In addition, farmhouses are painted with lead paint too, which I think some people forget.

So I think there are a lot of things that we are going to turn up.

Senator **Harkin**. You are talking about the older farmhouses?

Dr. **Rall**. Yes; and there are a lot of older farmhouses too.

Senator **Harkin**. Probably barns too, I suppose?

Dr. **Rall**. Yes.

Senator **Harkin**. Sheds, outbuildings, things like that.

Dr. **Rall**. Our conference on this will be July 12 and 13, down in North Carolina. We would be delighted if you would come and give us some of your anecdotal experiences. I think that could be very useful.

Senator HARKIN. July 12 and 13?

Dr. RALL. Yes.

Senator HARKIN. At the university?

Dr. RALL. Our institute down there.

Senator HARKIN. I could give you some, I probably would not be there, but I might send you some down.

Dr. RALL. Good.

TESTING OF NEW CHEMICAL COMPOUNDS

Senator HARKIN. I understand you began tests on approximately 10 new chemical compounds each year. The full process testing takes about 7 years, costs $1 million to $2 million per chemical.

I understand you believe it would be appropriate to initiate the testing of 25 to 30 new chemical compounds each year. What would it cost us in fiscal year 1991 to initiate tests on 30 new chemical compounds?

Dr. RALL. That, in our contract budget would require another $7 million to $7.5 million a year.

STIPEND FOR INTERNATIONAL RESEARCH

Senator HARKIN. Dr. Schambra, I understand the stipend for the International Research Fellows Program is $20,000. It has been frozen at that level since 1984.

That is even below the $27,000 provided for other postdoctoral fellowships or $30,000. I would like to get a better handle on what the average is. Why is it lagging behind? And do foreign governments supplement this in any way?

Dr. SCHAMBRA. The average stipend for the International Research Fellowship [IRF] is approximately $20,000, and has been unchanged since 1984. It has lagged behind other fellowship stipends because with no growth in funding for new awards, priority has been placed on maintaining the number of awards at a constant level, even at the cost of stipend increases. This cannot continue, however. Of the 90 awards in fiscal year 1989, only 4 received supplements from their governments. Many foreign governments do not have access to hard currency. Also, one-third of our IRF's come from developing countries which cannot afford to subsidize their national costs in the United States.

We would like to be able to raise the average award from the current $20,000 a year to about the $27,000 level, which is the median of fellowships for individuals at that level of professional development.

Senator HARKIN. What would it require to do that? How much money would be required for you to do that?

Dr. SCHAMBRA. We have calculated an additional $966,000 would be required in our 1991 budget and implement the necessary stipend increase. I would also like to mention that the stipend level for our Senior International Fellowship Program has not been increased since 1984 either. This award provides a $15,000 stipend plus a $15,000 foreign living allowance for midcareer American scientists to conduct advanced research abroad and bring new techniques to the United States.

SCIENTIFIC EXCHANGE FOR EASTERN EUROPE AND THE SOVIET UNION

Senator HARKIN. I appreciate that, Dr. Schambra.

One last thing, with what is happening in Eastern Europe and the Soviet Union, it seems like we have an opportunity here to greatly expand scientific exchange in those countries.

Are you proceeding along that line?

Dr. SCHAMBRA. Yes; we are doing the best we can. We certainly, as I know you and the rest of the world, have been quite fascinated by what is happening in the countries behind the former Iron Curtain.

One of our greatest opportunities today is to significantly expand international cooperation with Eastern Europe and the Soviet Union on health and biomedical research problems. We have surveyed the interest of NIH scientists in expanding cooperation with their colleagues in these countries and also have heard from many biomedical scientists throughout the United States about their interests. Areas for scientific collaboration have been identified, including AIDS, environmental health, cancer, and cardiovascular diseases. Many of our scientists believe that Eastern Europe and the Soviet Union offer unusual and important collaborative opportunities. They have also noted that highly competent Soviet and Eastern European biomedical scientists are eager to work directly with United States researchers. This could produce benefits for United States science. The Soviet Union and countries of Eastern Europe have expressed their desire in participating in FIC programs. There is a great interest in, and great gains to be achieved from, biomedical research cooperation with these countries.

An area where Americans and Eastern Europeans have a strong common interest is in combating the spread of AIDS.

We are, as I say, doing what we can within the resources available to try to meet some of those needs, and have also developed inhouse proposals for a substantially expanded effort in Eastern Europe which I would be pleased to submit for the record.

[The information follows:]

PROPOSAL FOR UNITED STATES-EASTERN EUROPE FUND FOR BIOMEDICAL RESEARCH COOPERATION

The political, economic, and social reforms occurring in Eastern Europe provide unprecedented opportunities for American scientists to cooperate with East European colleagues. Foreign policy priorities and the scientific benefits of joint research suggest there would be immediate value in the establishment of a program to support U.S.-East European biomedical research cooperation. If such a program is structured with flexibility, it could be rapidly responsive to new scientific opportunities and produce benefits for the East European technical community while contributing to long-term progress on U.S. biomedical research priorities.

The Fogarty International Center (FIC) of the National Institutes of Health (NIH) is in a unique position to implement such a program and to provide leadership in fostering contacts between East European and American biomedical researchers. As the focal point for NIH international activities, the FIC has a long history of direct collaboration with many countries of Eastern Europe including Poland, Hungary, Bulgaria, Yugoslavia and Romania. FIC facilitates the international activities of NIH by developing direct scientist-to-scientist linkages between U.S. and foreign researchers. In relation to Eastern Europe, FIC has the flexibility and mandate required to move quickly and efficiently to take full advantage of scientific and political opportunities if resources are available. FIC also has the necessary linkages to the foreign policy community.

A program to support U.S.-East European biomedical research collaboration through the FIC should be funded at a level of $4 to $5 million per year for a minimum of five years. These resources would generate long-term technical linkages, support research and research training, and expand scientist-to-scientist contact. The overall goal would be the development of collaborative relationships which would extend beyond the period of initial involvement. Specifically this fund for U.S.-East European Biomedical Research Cooperation would include five major components (with estimated costs for fiscal year 1990):

—Research grants for U.S. scientists to conduct collaborative research with Eastern European scientists (26 grants for $1,300,000);

—Training grants in U.S. institutions for Eastern European scientists and health professionals in the field of AIDS (20 trainees for $600,000);

—Research Fellowships to support Eastern European scientists in U.S. biomedical research laboratories for 1-2 years (40 fellowships for a total of $1,200,000);

—Short-term exchange visits (up to 6 months) between U.S. and Eastern European scientists to develop and promote research collaborations (50 exchange visits for a total of $400,000); and

—Scientific workshops to explore mutual interests, develop linkages and define areas of promising scientific collaboration (10 workshops for a total of $500,000).

PARTICIPATION

Countries involved in this initiative may include Bulgaria, Czechoslovakia, East Germany, Hungary, Poland, Romania, and Yugoslavia depending on the status of reform in each country and the availability of scientific opportunities. A parallel program could be established for the Soviet Union if circumstances warranted.

BUDGET

[Five year projected]

Year		Research grants	AIDS training	Two-year fellowships	Scientist exchanges	Workshops	Total
1:	Number	26	20	40	50	10	
	Cost	$1,300,000	$600,000	$1,200,000	$400,000	$500,000	$4,000,000
2:	Number	24	20	Yr. 1 35 Yr. 2 40	25	5	
	Cost	$1,200,000	$600,000	$2,250,000	$200,000	$250,000	$4,500,000
3:	Number	26	23	Yr. 1 35 Yr. 2 35	20	5	
	Cost	$1,300,000	$700,000	$2,100,000	$150,000	$250,000	$4,500,000
4:	Number	30	33	Yr. 1 35 Yr. 2 35	20	5	
	Cost	$1,500,000	$1,000,000	$2,100,000	$150,000	$250,000	$5,000,000
5:	Number	30	33	Yr. 1 35 Yr. 2 35	20	5	
	Cost	$1,500,000	$1,000,000	$2,100,000	$150,000	$250,000	$5,000,000

MANAGEMENT

The FIC will administer this initiative in close collaboration with the NIH Institutes, other components of the U.S. Public Health Service, the Department of State and others involved in international collaboration. FIC has extensive management experience in all areas of proposed program activity.

Senator **Harkin**. That concludes my questioning. I will have additional questions for each of you for the record that we will be submitting to you, and thank you for being here, and again, my personal thanks to each one of you who are doing such a fine, fine job.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

STATEMENT OF DR. MURRAY GOLDSTEIN, DIRECTOR

SUMMARY STATEMENT

Senator **HARKIN**. The next panel, Dr. Murray Goldstein, Director of the National Institute of Neurological Disorders and Stroke; Dr. Jay Moskowitz; Dr. James Snow; Dr. Ruth Kirschstein; Dr. Carl Kupfer, and Dr. T. Franklin Williams.

We will proceed just as we had with the previous panel in the order which I called them.

First, the National Institute of Neurological Disorders and Stroke. Dr. Goldstein, we are delighted to have you with us again. Your budget request is $512,210,000 about a 4.45-percent increase, and again, all of your statements will be made a part of the record in their entirety. If you could summarize or highlight what you think we should know, I would appreciate that.

Dr. **GOLDSTEIN**. Thank you very much, Mr. Chairman. This is the 40th anniversary at the Institute and the first year of the "Decade of the Brain," and I am particularly pleased to be able to share with you some very amazing results.

GAUCHER'S DISEASE

I have before you an exciting set of photographs. Within the last month we have had an exciting breakthrough. There is a terrible disorder known as Gaucher's disease, a genetic disorder primarily of children, which leads to disability and to death.

There has been no treatment for this disease and the picture on top is that of a child with the disease. You notice the child has a very large belly. The abdomen is bloated, not because of fluid, but because the child's liver and the child's spleen have grown in size. This child would have died in the near future.

Below it you have the picture of 3 months after treatment. Subsequently, the use of enzyme replacement therapy which was perfected in our own laboratories at the Neurology Institute at NIH.

This was so impressive, quite frankly, sir, we did not believe it. So, we tried it on 12 other patients and each responded dramatically. It is an amazing breakthrough. It is the first time in a genetic metabolic disorder that enzyme replacement therapy has been successful.

There are remaining questions to be answered. How long will this result last? Is this result something that is temporary now and 1 year from now ineffective? I do not know the answer to that, but I did want to bring it to your attention. We have had this important breakthrough and are looking forward to pursuing it with vigor.

It also sets an interesting stage for the treatment of other genetic disorders of the brain and nervous system. As you know, 25 percent, one-quarter, of all genetic disorders occur in the brain and nervous system.

So the nervous system is a common site of genetic abnormalities. We should not be surprised at that because of the anatomic and biochemical intricacies of the system. Unfortunately, there are many places that development and functioning can go wrong. But this breakthrough does set an important stage. As we progress and learn more about the genetic diseases of the nervous system: neurofibromatosis, Huntington's disease, dystonia; we now have one successful model that can be utilized as we learn more about possible treatments for those other diseases.

PARKINSON'S DISEASE

A second very important breakthrough has been the development of an exciting new drug, for the treatment of Parkinson's disease, deprenyl. What is of equal importance is that it is the first time a drug has been developed that has stopped the progression of a brain degenerative disease. This has never been possible before. For the first time, in the case of Parkinson's disease, we have such a drug.

It is now on the commercial market and readily available for patients with Parkinson's disease.

Senator **Harkin**. And it absolutely stops the progression?

Dr. **Goldstein**. It stops the progression of the disease. Now what I cannot tell you, as with Gaucher's disease, is for how long. That I do not know. We have continued the study in order to answer the how long questions. We decided, and it is a multimillion dollar study, to continue the study for 5 more years, to find out the long-term effects of the drug.

My own guess is that it will have long-term effects, literally stop the progression of a brain degenerative disorder.

STROKE AND ATRIAL FIBRILLATION

The third important breakthrough is one that will be reported in 2 weeks in the scientific literature. I am going to be a little diffuse in my telling about it because scientific journal editors get very disturbed when we scoop them.

There is a chronic disease of the heart of older people known as atrial fibrillation. It usually does not have any profound effect on the person who has this disease. It is sometimes a bit debilitating, but rarely life-threatening.

The threat of the disease is that it does send emboli to the brain because the heart is irregular and little pieces of a blood clot break off and go to the brain. This causes stroke and it is not unusual to cause stroke in elderly people.

We are just completing a study in which we now have a medication which clearly prevents this from happening. In a few weeks, this information will be available to physicians.

The point I am really trying to make, sir, is that after 40 years of generous support by the Congress for the Institute's program of basic research, we are now able to convert this information into clinically useful modalities. We are now entering the arena of clinical research and the development of improved methods of prevention and cure of brain disorders.

Within this year, we have had three important outcomes of successful clinical research that will have long-term consequences on the quality of life of persons with brain and other neurological diseases.

RESEARCH FAILURES

Now, let me tell you about three of our failures. One is Lou Gehrig's disease, ALS. We do not know what causes it. We still do not have any treatment to either prevent it or treat it. It is one of our failures. We are working on it, but I must admit, sir, we have not been successful.

A second failure is with stroke. The mortality rate from stroke has dropped 40 percent in the last 15 years. That is an amazing drop, but within the last 2 years, the incidence of new cases of stroke have begun to increase again. We are hard at work trying to figure that out. Why is it going up, when mortality continues to fall? We don't yet know.

We have very good data on stroke occurrences in white populations because the base for long-term studies have been on whites. We are now trying to find a population of blacks and orientals in which there is not a great deal of movement in and out of the community. This is absolutely necessary to find out if this increase is in fact occurring also in these minority populations.

We are presently working with two groups of investigators in an attempt to get those data.

PREPARED STATEMENT

Finally, our last failure is we still have done remarkably poorly in the treatment of head and spinal cord injury. We are working on that issue, but I have nothing of any positivity to report.

Sir, those are our successes and failures at the beginning of our 40th year. I would be pleased to answer any questions you might have for me.

[The statement follows:]

STATEMENT OF DR. MURRAY GOLDSTEIN

This year the National Institute of Neurological Disorders and Stroke (NINDS) celebrates 40 years of neurological and neuromuscular research conducted and supported by the Institute in its own laboratories and clinics and in other institutions across the United States and around the world. Since 1950 the Institute's efforts have contributed to steady progress in understanding, preventing, and treating the hundreds of neurological disorders that threaten and impair the quality of life of millions in this country and elsewhere. When NINDS was created only two neurotransmitters--the substances by which nerves talk to each other--were known to exist; today over forty substances are known to be involved with neurotransmission, many of them found in just the last ten years. In 1950 the standard of brain imaging was an X-ray; today we can chart the electrical, magnetic, biochemical, and metabolic landscape of the cortex and deeper brain structures. Just ten years ago we could only observe and chart the nerve damage caused by trauma or degeneration; now we know that damaged neurons can regrow and transmit impulses again and we are acquiring the tools to reduce or halt the progression of disease symptoms. Progress in the application of genetics, biotechnology, and new surgical approaches has been similarly dramatic.

The Congress and the President recognized the impact of neurological diseases on millions of Americans and expressed their belief in the potential of neurological research for even greater progress by designating the decade beginning January 1, 1990 as the "Decade of the Brain." This call for even greater effort on the part of the government and the public offers a unique opportunity for addressing the research, medical, and behavioral issues related to the human brain and its functions.

During this decade, the NINDS will continue to lead the national effort in neurological and neuromuscular research and research training. The labors of that mission have resulted in amazing discoveries: how nerve cells receive and transmit information; how the nervous system is organized and allows us to perceive, learn, and act; how viruses, the immune system, and defective genes create neurological disease; and, most importantly, how we can intervene with surgery, medication, or lifestyle changes to prevent, alleviate, or cure many neurological and neuromuscular diseases and disorders. We have made significant, but still only early progress in understanding stroke, multiple sclerosis, Parkinson's disease, rare neurogenetic diseases such as lipid storage diseases and neurofibromatosis, muscular dystrophy, and head and spinal cord injury.

Much has been accomplished--so much more remains to be done. The designation of the "Decade of the Brain" expresses the belief that past discoveries will lead to even greater achievements. I assure you that this belief is well-founded.

For the first time, we have evidence of a drug that can slow the progression of a neurodegenerative disease. Patients with early Parkinson's disease are being treated with deprenyl and/or tocopherol--a component of vitamin E--in a clinical trial supported by NINDS. Previous studies in an animal model of Parkinson's disease suggested that highly reactive free radicals (chemicals produced by metabolic reactions) could be responsible for some of the nerve cell loss found with the disease. Tocopherol can "soak-up" free radicals after they are formed and deprenyl can prevent their formation. The effectiveness of deprenyl was clearly confirmed by early results of the clinical trial; deprenyl delayed by many months the need for traditional antiparkinsonian treatment, which can have side effects and limited efficacy. For those patients, this meant more months of working and living a normal life. The results were so clear that the study directors took the unusual step of publishing the results from the study before its completion so that the findings could be disseminated to the medical community and patients could begin to benefit from the trial. Additional studies will elaborate on the long term utility of deprenyl and tocopherol in treating Parkinson's disease.

These findings represent a major breakthrough for Parkinson's disease patients and raise important questions about the applicability of the finding to other neurodegenerative diseases, such as Alzheimer's disease, Huntington's disease, and amyotrophic lateral sclerosis. We expect that this will be a lively area of research for the next several years.

Over the next decade, NINDS scientists and grantees can be counted upon to continue to make progress in finding disease-causing genes and genes that regulate normal components of the nervous system, as well as expanding our understanding of the genetic basis of nerve function. A technological breakthrough promises to further expand the potential of neurogenetics research. Scientists can now introduce genes into non-dividing cells--such as neurons--and obtain expression of those genes, thereby opening the way for new studies of neuronal growth and function. Particularly promising are efforts by intramural and extramural scientists to pinpoint the genes for Huntington's Disease and neurofibromatosis.

When a gene responsible for a disease is identified, a logical next step is to characterize the gene product whose abnormality may result in clinical disease. Such discoveries lead to the possibility that molecular genetics may be applied to the development of clinical treatments. For example, scientists have recently transplanted normal muscle precursor cells into animals genetically deficient for dystrophin, the normal protein which is absent or defective in Duchenne muscular dystrophy. The transplanted cells fused with the deficient muscle fibers and produced dystrophin. In a different animal model, treated dystrophic animals showed improvement in their symptoms and lived longer than untreated dystrophic animals. Preliminary steps are underway to develop the cell transplant technique for potential application in human patients. The cure for muscular dystrophy is in the offing.

Increased understanding of the genetic mechanisms of neurological disease allows us to work toward immediate and long-term strategies. For instance, while intramural scientists continue to make significant progress in enzyme replacement therapy for Type I Gaucher's disease, they are also working on a more fundamental treatment using gene replacement techniques. The scientists have inserted the human gene for the enzyme missing in Gaucher's disease into mouse bone marrow, which then produced the enzyme, human glucocerebrosidase. Additional work must be done before determining the utility of this technique in humans; but if successful, clinicians would have a method to treat Gaucher's disease that could permanently alleviate the disease. In another example, data from the NINDS-supported Huntington's Disease Roster show that children of affected fathers develop the disease at a much earlier age than children of mothers with HD. It is theorized that the mechanism is a chemical change imposed on the Huntington's disease gene. If so, this may present an opportunity to intervene and "turn-off" the gene and delay the onset of disease.

We have in place a framework of epidemiologic studies, clinical trials, and laboratory investigations to tackle stroke, this nation's third leading killer and a major cause of disability. Stroke affects all segments of the population. Stroke incidence is now again rising, but we don't know why. Even low birthweight infants suffer mortality and morbidity resulting from brain hemorrhage. We are looking forward to the results of an NINDS-supported trial to test the efficacy and safety of a drug called indomethacin to prevent brain bleeding in these infants. Two ongoing studies in minority populations are expected to reveal clues about the greater occurrence of stroke in minority groups; more studies of this nature are being sought.

One of the key research issues in stroke over the next decade will be the medical management of patients while stroke is occurring. Much of the injury occurs over several hours when tissues die as a result of lack of oxygen and the cascade of physiologic effects that follow. Interventions under study include the regulation of hydrogen ions, alteration in brain temperature, inhibition of excitatory amino acids, and regulation of blood flow to damaged tissues. Blood sugar levels have also emerged as a factor in the occurrence of silent stroke, transient ischemic attacks that often precede a major stroke, and tissue damage following a stroke. Better medical management will mean the difference between someone who returns to the activities of daily living versus someone who is left paralyzed or speechless and dependent on family and health care services to survive.

Surgical and medical strategies have greatly improved the outlook for people with epilepsy. There remains, however, a core of patients whose seizures are not controlled--they have more than one seizure a month--even with state-of-the-art treatment. To help these people, NINDS grantees and intramural scientists are working on a two-pronged attack to screen drugs for their anti-epileptic potential and to understand the physiology of how nerve cells fire. Knowing how nerve cells are regulated will lead to improved medications to stop nerve cells from firing in the uncontrolled, explosive manner characteristic of seizures.

Amyotrophic lateral sclerosis (ALS, or "Lou Gehrig disease") is the best known of the motor neuron diseases. These disorders have been particularly resistant to efforts to identify a causative factor or therapeutic agent. Though the pathogenesis remains unknown, investigators are encouraged that we now have the tools and methodologies to mount more targeted investigations of the motor neuron degeneration characteristic of ALS. For instance, advances in neurobiology provide the means to study the role of neurotransmitters, their receptors, and nerve growth factor. Further clues to the disease are expected to come from the study of the structure and function of the affected nerve cells and tracts as well as genetic factors which can be found in relation to the disease.

The devastating effects of AIDS are particularly apparent in the nervous system. Some thirty percent of AIDS patients experience neurological complications early in the course of their illness; more than seventy percent suffer from neurological problems as the disease progresses. Recent findings indicate that the viral material in neuro-AIDS differs from that in patients who do not exhibit neurological involvement. Examining the mechanism and implications of this phenomenon is a high priority.

Head injury is the leading cause of death and disability in children and young adults. In addition, each year 10,000 to 12,000 Americans are disabled by trauma to the spinal cord. Though we are still working towards complete understanding of the mechanisms of trauma to the nervous system, we have exciting leads for the development of treatment strategies.

Underlying the advances I have described here--and the source for emerging clinical treatments over the next decade--is a vigorous intramural and extramural research agenda in the basic neurosciences. Studies in neurophysiology and neurochemistry will be the wellspring of potential therapeutic agents. Scientists are seeking mechanisms to allow drugs to cross the blood-brain barrier more easily and get to where they are needed in the brain. Further elucidation of the metabolic and cellular events responsible for tissue damage--due to stroke, traumatic brain injury, spinal cord injury, and epilepsy--will be facilitated by advances in tissue culture systems. The exploration of nerve growth factors and the conditions necessary to encourage and guide nerve cell growth and repair will contribute to methods of restoring nervous system functions. Developmental neurobiology studies demonstrate that cell-to-cell interactions are important for regulating growth of glial cells; these findings feed directly into understanding of the formation and growth of neural tumors. Insights into neurotransmitters and the coordination of neural networks will expand our understanding of learning disabilities, autism, sleep disorders, and normal cognitive functions such as learning and memory.

The neurosciences are on the verge of a new era. The consensus in the scientific community is that, amazing as past discoveries have been, they are truly only a glimpse of what we can expect throughout the "Decade of the Brain" from both basic neuroscience discoveries and clinical neurological research.

Mr. Chairman, the FY 1991 budget request for this Institute is $512,212,000. I am pleased to answer any questions you might have.

BIOGRAPHY OF DR. MURRAY GOLDSTEIN

October 13, 1925, New York, New York

EDUCATION: B.A., New York University, 1947; D.O., Des Moines Still College of Osteopathic Medicine, 1950; M.P.H., University of California, School of Public Health, 1959; Mayo Clinic (Neurology), 1968.

PROFESSIONAL HISTORY: Director, NINDS, 1982-present; Acting Director, NINCDS, 1981-1982; Deputy Director, NINCDS, 1978-1981; Medical Officer, Commissioned Corps, PHS (Assistant Surgeon General), 1953-present; Director, Stroke and Trauma Program, NINCDS, 1976-1978; Director, Extramural Programs, NINCDS, 1961-1976; Visiting Scientist, Mayo Clinic and Graduate School, Rochester, Minnesota, 1967-1968; Chief, Special Projects Branch, NINCDS, 1960-1961; Assistant Chief, Research Grants Review Branch, DRG, 1959-1960; Acting Chief, Section on Virus Diseases of the CNS, Bureau of Acute Communicable Disease, California State Department of Public Health, 1958; Director, Epidemiology and Biometry Training Grant Program, DRG, 1956-1958; Assistant Chief, Grants and Training Branch, NHI, 1953-1958; NIH Representative, DOE Interagency Committee on Handicapped Research, 1982-present; Member, DHHS Task Force on Alzheimer's Disease, 1983-present; Chairman, DHHS Interagency Committee on Spinal Cord Injury, 1986-1987; Commissioner, DHHS National Commission on Orphan Diseases, 1986-present; Chairman, DHHS Interagency Committee on Head Injury, 1988-present.

PROFESSIONAL ORGANIZATIONS: American Academy of Neurology; American Association for the Advancement of Science; American Heart Association, Council on Stroke; American Neurological Association; American Osteopathic Association; Member, Board of Directors, John P. Robarts Research Institute, London, Ontario, Canada; Society for Neuroscience; The American Parkinson Disease Association, Medical Advisory Board; United Cerebral Palsy Research & Educational Foundation, Board of Directors; Consultant (Neurology), Pan American Health Organization; Consultant, World Health Organization Program on Neurosciences; Chairman, World Health Organization Task Force on Cerebrovascular Disorders; Commission on Alternative Health Care, U.S. Olympic Council on Sports Medicine; Councilor, Neurotrauma Society; Board of Directors, National Stroke Association.

HONORS, AWARDS: Beta Alpha Epsilon, Biology National Honor Society, NYU; Psi Chi, Psychology National Honor Society, NYU; Sigma Alpha, Osteopathic Scholarship National Honor Society, College of Osteopathic Medicine; Delta Omega, Public Health National Honor Society, University of California; Doctor of Science (Hon), Kirksville College of Osteopathic Medicine; Doctor of Laws (Hon), New York Institute of Technology; Doctor of Science (Hon), University of New England; Doctoris Honoris Causa, Medical University of Pecs, Hungary; Doctor of Science (Hon), Ohio University; 2nd Vice President, American Neurological Association; Silver Star, Purple Heart, U.S. Army; Meritorious Service Medal, Public Health Service; Distinguished Service Medal, U.S. Public Health Service; Founders Day Medal (S.S. Still Medal), University of Osteopathic Medicine and Health Sciences, Des Moines, Iowa; Patenge Medal of Public Service, Michigan State University; Marjorie Guthrie Award, The Huntington's Disease Society of America.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much. When I get back to the questioning I'd like to address what you said in your opening statement about damaged neurons regrowing and transmitting impulses again. If that is the case, why can we not make some progress in understanding why, if you damage your spinal cord, why that cannot be used to transmit again. We will get to that later.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

HEAD INJURY RESEARCH

Question. Why is there no funding requested in your FY 1991 budget for additional head injury research?

Answer. The funds requested for FY 1991 will be used primarily to maintain ongoing activities and to support the related cost of living increases. Traumatic brain injury continues to be a priority research area of the Institute and steps have been taken to expand research in this area. For example, NINDS has recently established new head injury clinical research centers at Boston University in Boston, Massachusetts and at the Baylor College of Medicine in Houston, Texas. The Boston Center primarily addresses the study of memory disorders after head injury, and the Baylor Center is for the evaluation of new treatments of brain dysfunction due to head injury.

Question. Tell us about the research opportunities in head injury and the status of the recommendations of the interagency task force?

Answer. Research issues of immediate concern focus on understanding the basic pathology to the brain resulting from traumatic brain injury (TBI) and clinical research on how to remedy that pathology. We now have substantial evidence that if the damaged brain tissue is protected within four hours of injury, permanent damage can be prevented in a large proportion of cases. There is a need to define the molecular and cellular characteristics of primary and secondary injury to the brain and their relation to outcome. We must also define the biological events that lead to acute and prolonged coma, and develop methods to restore wakefulness. Evidence suggests that injured neurons can survive and the regrowth of injured axons is possible; this is an active area of investigation for restitution of lost function. Additional research opportunities now available include development of improved experimental brain injury models and new methods for neurological and neurosurgical interventions.

The Interagency Head Injury Task Force, at the request of the House Appropriations Committee, is preparing a second report which sets forth a series of implementation steps to carry out the first two recommendations of a proposed strategy presented in its February 1989 report. The two recommendations focus on (1) the designation of a lead Government agency for Federal TBI coordination and planning among the federal Departments and agencies and with the states and the private sector and (2) the establishment of TBI as a category in reporting systems.

STROKE

Question. Dr. Goldstein, as you know the mortality rate related to stroke is going down but in incidence rate of stroke is going up. For many years the incidence rate was also going down but in approximately 1987 it turned around and started to increase.

Why is the incidence rate of stroke increasing?

Answer. The incidence rate of stroke is again increasing. We do not know why but there may be several reasons. It is now possible to diagnose stroke in patients, who in the past were misdiagnosed, by using computerized tomographic (CT) or magnetic resonance (MR) scans. These diagnostic refinements can add to the number of strokes diagnosed that might not have been diagnosed a decade or more ago. In addition, the population as a whole is surviving longer with decreased or delayed mortality related to other diseases such as heart disease. Since strokes tend to occur more often in older individuals, longer survival with other diseases increases the likelihood of living to an age when the stroke rate is higher. The incidence of stroke reflects the number of strokes that will occur in a population of 100,000 in one year. Since the population is increasing and at the same time the proportion of older citizens is increasing, the total number of strokes occurring in the United States may well increase significantly during the next two decades.

DECADE OF THE BRAIN

Question. A great deal has been said about the Decade of the Brain. Essentially, new imaging technology and new discoveries have brought us to a point where a great deal of additional research could be done with very beneficial results. Your 1991 budget, however, appears to be relatively business as usual.

What are the major initiatives you would like to pursue in the content of the Decade of the Brain, if additional funding were available?

Answer. The "Decade of the Brain" recognizes the advances made in the basic and clinical neurosciences and the tremendous opportunity for further achievement in neurological and neuromuscular research. Given additional funds, three major initiatives we would pursue are head injury research, neurogenetic research (genetic disorders of brain and spinal cord), and clinical trials. The clinical trials would include the development and evaluation of improved treatments for head and spinal cord injury, epilepsy, multiple sclerosis, stroke, Parkinson's disease, and genetic disorders of the nervous system. In response to the recommendation of the Interagency Head Injury Task Force, the NINDS would establish, over a period of three years, a national network of 15 regional head injury research centers of excellence which would also collaborate with local trauma units to develop and evaluate new forms of treatment and provide an efficient means for disseminating emerging knowledge for community use. In the area of neurogenetic disease, the Institute would focus on the localization and identification of the specific genes responsible for the disease, the utilization of enzyme replacement therapy to provide for treatment and the development of gene replacement methodologies to provide a cure.

With the designation of the "Decade of the Brain", the Institute's advisory council has appointed a national panel--including members of the voluntary and professional groups involved in the neurosciences--to develop a Decade of the Brain research implementation plan. The Plan will be an "action agenda" outlining the research objectives, administrative actions, and resources needed for the decade, and setting research priorities. We look forward to the recommendations outlined in the Plan to refine and expand on the research initiatives to be undertaken in the Decade of the Brain.

GENETIC NEUROLOGICAL DISORDERS

Question. As you know, 25 percent of all genetic disorders are neurological. What assistance do you hope to have from the Human Genome Project with regard to solving the mystery of these several thousand genetic disorders?

Answer. Impressive new findings have shown how alterations in the human genome affect the body's chemistry leading to Huntington's disease, Alzheimer's disease, muscular dystrophy, neurofibromatosis, and many other genetic disorders of the neurological and neuromuscular systems. Particularly promising are efforts by NINDS intramural and extramural scientists to pinpoint the genes for Huntington's Disease and neurofibromatosis. The NINDS's Laboratory of Molecular and Cellular Neurobiology is one of the few laboratories in the world which can conduct large scale DNA sequencing of neurotransmitter receptor genes and human chromosomal regions to which neurological disorders with a genetic basis have been mapped. As part of its ongoing projects, it has been developing sequencing strategies and technologies which will allow the sequencing of very large regions of DNA in a highly efficient manner. Because of this, the National Center for Human Genome Research is considering collaborating with the NINDS to sequence the X chromosome which contains the genetic material believed to be implicated in many neurogenetic disorders, including one form of muscular dystrophy.

In addition, we expect that many of the discoveries stemming from the Human Genome Project will also further the understanding of the genetic basis of neurological and neuromuscular disorders. The "library" of gene sequences will provide information essential to the efficient identification of specific genetic alterations. Identifying genes and gene products whose absence or deficiency results in clinical disease assures greater possibilities for the development of clinical treatments.

HUMAN FETAL TISSUE RESEARCH

Question. In March 1988, the Department of Health and Human Services imposed a moratorium on research involving the transplantation of human fetal tissue obtained from induced abortions. This moratorium was extended indefinitely in November 1989 by Secretary Louis Sullivan.

Last year, you indicated that the moratorium has slowed progress in the area of using implants to replace injured or destroyed brain cells, particularly as a possible treatment for Parkinson's patients. How is this research progressing in the private sector? What about abroad?

Answer. Researchers in the United Kingdom and Sweden reported in early February that a patient with advanced Parkinson's disease who had a fetal brain tissue transplant showed marked improvement of neurochemical functioning, motor performance, and the activities of daily living. The data suggested that human fetal neurons can survive, grow, and restore the dopaminergic neurotransmission that is deficient in Parkinson's disease. Fetal tissue implantation has also been performed on patients in Cuba, Mexico, and China. It has been difficult to evaluate the results from these three counties.

At the University of Colorado, investigators have performed fetal tissue implantation on two Parkinson's patients. At fifteen months after surgery, the first patient shows similar degrees of improvement to the individual in the Swedish study. The results of the Colorado case will soon be published. Six patients who have received fetal implants at Yale University are now being evaluated. The results so far are encouraging enough to foster continuation of the project. It should be noted that, in view of the moratorium, neither of these research projects is supported by NINDS funds. Also, since there is no federal involvement, the research results are limited to informal communications rather than progress reports.

Question. Are you supporting transplantation research projects that use human fetal tissue from sources that are not prohibited by the moratorium, e.g., spontaneous abortions, stillborn? If not, why? If so, what information has been obtained from such investigations?

Answer. The NINDS is not supporting transplantation research using human fetal tissues, derived by any means, transplanted into patients. Although the moratorium on fetal tissue implantation research allows for the use of material from spontaneous abortions, these cells are generally not suitable for transplantation due to the greater likelihood of genetic abnormalities and the lack of sterile conditions at the time of the spontaneous abortion. To implant such tissues into human brain raises serious scientific and medical problems.

AIDS

Question. Do you have anything new to report on the neurological abnormalities associated with HIV-infection in children?

Answer. Two thirds of children under treatment for AIDS have neurological abnormalities. AIDS in children is a special disease, which although unpredictable in its course, causes progressive peripheral nervous system degeneration and brain injury leading to mental retardation and death. NINDS grantees and scientists continue to refine our understanding of the progression of HIV infection in the nervous system of affected children and the subsequent cognitive and motor effects. For instance, we know that children with HIV infection of the central nervous system exhibit different cellular and tissue changes as compared to infected adults. Behaviorally, these children may be severely retarded and withdrawn. Further progress may lead to earlier identification of children at risk for neurological involvement, earlier diagnosis, and improved therapeutic interventions.

Question. Have drugs like AZT been demonstrated to be effective in improving adverse effects of the AIDS virus on the nervous system?

Answer. In 1988, investigators reported that adult patients who received AZT experienced improvement in a wide range of cognitive functions including attention, motor skills, and general brain activity when compared with a group treated with placebo. These findings were confirmed by clinical observations and nerve-conduction studies, and by positron emission tomography. In a separate study at the National Institutes of Health, HIV-infected children with resultant encephalopathy were treated with AZT. The children showed improvement in neurodevelopmental abnormalities and increases in IQ scores.

Research supported by the Institute aims to determine how the virus enters the brain and how it damages nerve cells. Understanding these phenomena will allow researchers to prevent or ameliorate the neurological symptoms associated with AIDS.

Question. Do the AIDS vaccines currently under investigation seem to be effective in relieving any of these neurological abnormalities?

Answer. It is premature to comment on the effect of vaccines as therapeutic agents. Proposed vaccines would be tested in individuals prior to the development of full-blown AIDS, usually before the onset of neurological symptoms. A successful vaccine would prevent infection by the virus and advancement of the symptoms of AIDS, including neurological abnormalities.

STROKE

Question. How are you doing at addressing criticisms of the inadequate efforts in investigating stroke in black populations?

Answer. Progress is being made in addressing the problem of stroke in blacks. The NINDS has announced its interest in receiving applications for research in this area. Unfortunately, few applications have been received to date. Of course, we would like to have more, but we recognize that the preparation for a reliable study requires extensive planning. We are working with one potential applicant to define a suitable population to study. The population will have to be available over time for evaluation. We also know of several other proposals that are being developed; our staff are working with these investigators. In addition, Institute representatives are speaking at national meetings of stroke researchers to emphasize the importance of this issue and aggressively encouraging the interest of appropriate scientists in pursuing research on this topic.

Question. Last year, you expressed a major concern with an apparent trend of increasing incidences of new stroke cases in the black population over the past few years. Is that trend continuing? Do you have any additional information on the reason for this? What about other ethnic groups?

Answer. Additional information has been forthcoming on stroke in blacks and other ethnic groups. None of the data has the precise answers to the questions that we all want answered, but there are suggestions that Hispanic Americans have a higher stroke and stroke mortality rate than white Americans. The higher stroke rate in black Americans, both males and females, continues to be confirmed. The strokes in blacks tend to occur at a younger age and be of a type associated with deeper areas of the brain. In whites, the type of strokes tend to be those associated with areas on the surface and the base of the brain. Similar to the population as a whole, a higher number of strokes can be expected in blacks in coming years if the incidence rate of stroke does not decline. This is particularly true for blacks, because that part of the population has grown more rapidly and blacks have strokes at a younger age. Another group of patients are now being recognized. Strokes are occurring in young people between the ages of 15 and 25 due to drug abuse. We are actively pursing this recent finding.

PET CENTERS

Question. What is your FY 1991 request for positron emission tomography (PET) centers?

Answer. The FY 1991 estimate for PET centers is $11,480,000.

Question. How many PET centers would this request support?

Answer. This request will provide support for seven PET centers.

Question. Last year, you indicated that you were considering collaborating with NIDA on a project in which PET would be used to study the effects of cocaine and other addictive drugs on the brain. How has that discussion progressed?

Answer. We continue to maintain an interest in the potential for collaboration with NIDA on a project in which PET would be used to study the effects of cocaine and other addictive drugs on the brain. Toward that goal, we have identified several areas of research that would be appropriate for collaboration by NINDS and NIDA and are hoping to be able to initiate mutually beneficial endeavors.

Question. Are any of the PET centers currently being funded by your Institute engaged in studying why the brain of an addict becomes addicted to cocaine and other drugs?

Answer. One of the PET Centers currently funded by the NINDS has been doing a pilot study using tracers to study changes in the brain of patients addicted to cocaine and to heroin. In addition, changes in the brain were being studied of recently detoxified cocaine-dependent patients. Pilot studies such as these would provide the opportunity not only to determine what changes accompany the use of addictive substances but also to explore questions related to the reversibility of those changes. This information has important implications for exploring the mechanisms underlying successful treatment programs.

PET CENTERS/JAVITS CENTERS FOR EXCELLENCE

Question. What has been the impact of negotiated reductions on activities in your centers, particularly for PET studies and the Javits Centers of Excellence?

Answer. The NINDS has supported four Senator Jacob Javits Centers for Excellence in the Neurosciences. The NINDS support for these centers is now being terminated. By this action, we recognize that we lose the unique multidisciplinary environment of Javits Centers which have already fostered productive and creative investigations. The centers were designed so small groups of investigators--the most outstanding and innovative groups in the country--could work collaboratively on fundamental issues in nervous system structure and function.

In an effort to maintain the current numbers of centers and program projects, the NINDS has just begun to phase in a $750,000 ceiling for new and competing grant applications. This action will translate into utilization of PET technology in fewer studies. Plans to expand the use of PET to studies of various neurotransmitters, and studies of patients with Alzheimer's disease, Parkinson's disease, cognitive brain disorders, and movement disorders are on hold.

RESEARCH ACCOMPLISHMENTS

Question. Can you describe the three or four most significant research advances funded by NINDS during the past year?

Answer. During the past year we have seen major achievements from several NINDS-funded intramural and extramural projects. One of the most important research advances of the past year was the finding from an NINDS-supported clinical trial that the drug deprenyl could delay the progression of early Parkinson's disease. This is the first time any treatment has proved beneficial in slowing the progression of a degenerative disease of the brain. We are continuing to study this treatment to determine the long-term effects.

In an important intramural study, children with Gaucher's disease have had truly amazing benefits from enzyme replacement therapy. Their anemia has been corrected, the enlarged spleens and livers have decreased in size, and, most important, their activities of daily living have returned to nearly normal.

Promising results have been obtained in a small study of a vaccine to prevent AIDS in previously infected chimpanzees. The vaccine, made from the core of the AIDS virus, appears to eliminate the virus from the infected animals. This intramural study is part of a larger collaborative effort to develop an effective and safe AIDS vaccine.

Most technologies for transferring genes into cells require that the cells be able to divide. In the past, this has eliminated the potential use of these technologies in brain cells. A new technique for introducing genes into non-dividing cells--such as neurons--and obtaining expression of those genes has now been developed. This technology should greatly facilitate the study of nerve cell development, differentiation, and function, as well as approaches for altering gene defects in nervous system diseases. Gene replacement therapy for neurological disorders now becomes a possibility for the future.

RESEARCH PRIORITIES

Question. What do you consider to be the highest research priorities for your institute within the President's budget? What would you initiate if additional resources were available?

Answer. Within the President's budget, our highest priorities are head injury research, neurological genetic disease research, and clinical trials.

Given additional resources, we would restore funding to awards that have been reduced; restore funding to centers; expand research on head injury, neurogenetic disorders; and initiate seven high-priority clinical trials.

CLINICAL TRIALS

Question. Tell us about the clinical trials you would fund if resources were available.

Answer. We have seven clinical trials in the planning process that could be supported in FY 1990.

The proposed trials include two new treatments for multiple sclerosis; a clinical trial of enzyme replacement therapy for Gaucher's disease (this trial would build on the successful results obtained by intramural scientists); and a trial of medical treatment for recurrent stroke prevention.

We also would give high priority to a study of surgical treatment for seizures--for many people surgery is the only chance for a normal life--and a study of a drug treatment for status epilepticus. People with this condition have recurrent seizures, one after another; the condition can be life-threatening.

Finally, we would also like to do a new study of deprenyl treatment for Parkinson's disease to follow up on the very exciting evidence that deprenyl is the first drug to delay the progression of a neurodegenerative disease. The new trial would be to determine the long-term effects of deprenyl.

We have six other trials in the planning process that could be supported in FY 1991. These include a treatment for head injury and a treatment for spinal cord injury. We would also support the National Acute Spinal Cord Injury Study III. Two other trials would determine the efficacy of a calcium channel blocker and an anti-convulsant to treat patients with partial seizures. We also would conduct a trial on the use of monoclonal antibodies to treat multiple sclerosis.

AUTISM RESEARCH

Question. In 1989, the movie "Rain Man" provided many in the public with their first exposure to the severe developmental disability know as autism. As that movie recedes from public attention, I am concerned that NIH not recede from appropriate efforts to combat this condition. Please describe for the record the Institute's FY 1991 plans for encouraging, funding, conducting, and collating research on the causes and treatment of autism. Please also outline the Institute's preliminary thoughts on autism research efforts for future years so that the Committee can appreciate how proposed FY 1991 expenditures for this purpose relate to longer term efforts to understand and combat this condition.

Answer. The Institute will continue in FY 1991 to promote its recent program announcement to encourage both basic neuroscience and clinical research concerning autism. It is quite clear that autism is a neurological defect in brain functioning. It is not a "behavioral disorder". A pediatric neurologist with a special interest in autism has been recruited to the NINDS staff to develop further the Institute's research program on autism. New research opportunities in autism and the other neurological behavior disorders were identified in the Decade of the Brain report to the House Committee on Appropriations. The Institute plans to pursue vigorously these opportunities such as the preliminary finding of underdeveloped areas of the cerebellum in some patients and the association of subtypes of autistic patients with the fragile X chromosome.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

GAUCHER'S DISEASE

Question. Dr. Goldstein, I have been informed by the Gaucher's Disease Foundation that scientists at the Institute have made significant progress in the treatment for Type I Gaucher's Disease in recent months. Would you describe this progress for the Committee?

Answer. Children with Goucher's disease lack an important enzyme that is responsible for metabolizing fatty material in the body. Without the enzyme, fatty substances build up in tissues and organs and lead to an enlarged spleen, liver, severe anemia, mental retardation, bone pain and fractures. In some cases, more severe neurological complications may occur. Type I Gaucher's disease afflicts approximately 20,000 people in the United States.

A team of NINDS intramural scientists, led by Dr. Roscoe O. Brady, have had great success with an enzyme replacement therapy for these children. The enzyme, isolated from normal human placental tissue, was administered to 13 Gaucher patients. These patients have had remarkable clinical benefit. Their anemia has been corrected, the size of the enlarged spleens and livers has decreased, and magnetic resonance imaging indicates that there is skeletal improvement. In addition, many have been able to return to normal daily activities, and they all emphatically state that the quality of their lives is greatly improved. Seventeen (17) Gaucher's patients have acted as controls in this clinical trial. They have not yet received the enzyme. Attempts are now being made to determine the minimal required doses, and to find a means of prolonging and activating the actions of the enzyme.

In related work, the same group of investigators is attempting to develop other approaches to enzyme replacement therapy. Investigators have inserted the human gene for the enzyme into mouse bone marrow cells in the laboratory, which have then produced the human glucocere-brosidase enzyme. Additional work must be done before determining the utility of this technique in humans but, if successful, clinicians would have a method to treat Gaucher's disease that would be permanent.

Question. Does the NINDS have sufficient resources to continue to build upon these research findings in FY 1990? What are the implications of not proceeding with further clinical trials at this time?

Answer. We do not have adequate funds in FY 1990 or FY 1991 to build upon these research findings without impacting other clinical research projects. Although the studies with enzyme replacement therapy so far are very positive and encouraging, many questions about the treatment remain unanswered. For instance, we need to know the optimal doses of enzyme and the long-term efficacy of the treatment. The intramural studies in Gaucher's disease are continuing, at a reduced level commensurate with the available resources, but certainly an increased level of effort is justified by the amazing results obtained already.

Question. Has the drug been approved for use by the FDA?

Answer. The FDA has released a treatment IND for the enzyme, so that people can now buy the enzyme with individual FDA approval. There is a plan to submit a new drug application (NDA) request by mid-March. If the review is expedited--which is expected--approval could be received by mid-summer. Even with FDA approval, patients must deal with the issue of cost of the drug, which is expensive.

CLINICAL TRIALS

Question. Dr. Goldstein, how many clinical trials have been approved in FY 1990? How many of these have received funding?

Answer. Eight new clinical trials have been approved for funding in FY 1990, although additional applications may be received prior to the end of the fiscal year. Of the eight trials approved, one will be funded.

Question. How many will you be able to fund under the FY 1991 budget request? Which ones will not receive funding?

Answer. No new clinical trials will be funded under the FY 1991 budget request; only ongoing clinical trials will be funded. There are six proposed new trials in the planning process that could be funded. These include a clinical trial for the treatment of acute head injury and a trial for the treatment for acute spinal cord injury. We would also support the National Acute Spinal Cord Injury Study III. Two other trials would study the efficacy of a calcium channel blocker and an anticonvulsant to treat patients with partial seizures. We also would conduct a trial on the use of monoclonal antibodies to treat multiple sclerosis.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

STATEMENT OF DR. JAMES B. SNOW, JR., DIRECTOR

ACCOMPANIED BY DR. JAY MOSKOWITZ, ASSOCIATE DIRECTOR FOR SCIENCE POLICY AND LEGISLATION, NATIONAL INSTITUTES OF HEALTH

SUMMARY STATEMENT

Senator HARKIN. Dr. Snow, Institute of Deafness and Other Communication Disorders, we are delighted to have you with us as the first permanent Director of the National Institute on Deafness and Other Communication Disorders.

You set another precedent in being the first senior scientist recruited to serve at NIH from the private sector in many years, and we are delighted that you have agreed to lead this very important endeavor.

As you know, I have a strong interest in your Institute and want to follow what you are doing very carefully and want to be as supportive as possible.

I also want to give my public thanks again to Dr. Moskowitz next to you for helping to establish the Deafness Institute and to get it going for the last year, and I know you are delighted to be back in your other position again and have Dr. Snow on board, but you have done a great job in getting it going and I really appreciate it very much.

Dr. Snow, your request for next year is $122.85 million or a 4.48-percent increase. Again, welcome and please proceed.

Dr. SNOW. Thank you very much, Mr. Chairman. In the 1½ years since the Institute was created by the Congress great strides have been made. We are particularly indebted to Dr. Jay Moskowitz for his very able stewardship that he provided the new institute during its initial development. Our goal is to maximize the gains that can be realized from research on human communication.

The NIDCD is pleased to join with other institutes at the NIH in celebrating the "Decade of the Brain." Neurobiology is an important component of our research portfolio, both extramurally and intramurally. An example of the focus of the NIDCD on neurobiology is neural regeneration. Regeneration of nervous tissue after injury and illness occurs in very few places in the human body. Interestingly, nasal neuroepithelium is one tissue that does have the ability to regenerate. Research in this area has profound implications for the repair and regeneration of the nervous system.

Scientists supported by the NIDCD have utilized the tools of molecular biology and molecular genetics to uncover important information on how human communication systems work at a fundamental level. I am very pleased to report that the gene for Usher's syndrome has been found on chromosome 1 by NIDCD-supported scientists. As you may know, Usher's syndrome causes deafness and blindness. These are areas that I intend to encourage for development and expansion.

Noise exposure represents the most common preventable cause of hearing loss today. The NIDCD sponsored a consensus development conference on noise and hearing loss at the NIH from January 22d to the 24th of this year. The statement drafted by the conference panel provided recommendations and avenues for future research related to noise and hearing loss.

One-half of our children have ear infections before they reach their first birthday, and 9 out of 10 children have ear infections by the time they are 6 years old. Otitis media is the leading cause of acquired hearing loss before age 10. The NIDCD, in collaboration with the NIAID, and the NICHD, is issuing a solicitation for research on a vaccine against otitis media.

Institute supported scientists have made great advances in therapeutic approaches to speech, voice and language disorders. This year investigators in the NIDCD intramural program were the first to demonstrate a successful treatment for voice tremor. I intend for our intramural program to provide a model to the scientific community in molecular biology and molecular genetics, to conduct clinical trials of promising new therapies and to serve as a national training resource.

Last year we reported to you on our research plan, the national strategic research plan. We now have a training plan. We are establishing a Physician-Scientist Award. Special emphasis will be placed on research training of underrepresented minorities and communicatively impaired individuals.

PREPARED STATEMENT

We plan to award several national multipurpose research and training centers this year. In addition, the Institute has undertaken a number of activities toward the development of an information clearinghouse.

Mr. Chairman, the fiscal year 1991 budget request favors basic research and totals $122,847,000. I will be pleased to answer any questions you might have.

[The statement follows:]

STATEMENT OF DR. JAMES B. SNOW, JR.

I am honored to appear before this Committee as the first permanent Director of the National Institute on Deafness and Other Communication Disorders (NIDCD). In the year and a half since the Institute was created by the Congress great strides have been made. We are particularly indebted to Dr. Jay Moskowitz for the very able stewardship he provided for the new Institute. Under his superb leadership, a fully functioning administrative staff was assembled and all of the legislative mandates for the NIDCD have been initiated or planned. Excellent extramural and intramural scientific programs were transferred to the new Institute and we intend to build on that strong foundation. Our goal is to maximize the gains that can be realized from research on human communication. We are supporting research across the entire biomedical spectrum, from basic research to clinical studies to technology transfer and to prevention and rehabilitation. The basic research is building a foundation for the next generation, while many of the clinical and rehabilitation programs are aimed at helping those with disabilities today, improving their lives. I am very pleased to be able to share with you selections from exciting scientific advances from our areas of science as well as highlights of research plans of the Institute.

The NIDCD is pleased to join with several other Institutes at the NIH in celebrating the Decade of the Brain. Neurobiology is an important component of our research portfolio, both extramurally and intramurally. The NIDCD observed its first anniversary this October and elected to celebrate with a scientific lecture on the cutting edge of neurobiology and auditory research. An example of the focus of NIDCD on neurobiology is in neural regeneration. Regeneration of neural tissue after injury and illness occurs in very few places in the human body. Interestingly, nasal neuroepithelium is one tissue that does have the ability to regenerate. As scientists supported by the NIDCD seek to unlock the clues to why olfactory tissue has this ability, the information they learn can be applied to other nonregenerative tissues. Other NIDCD-supported researchers have determined that olfactory neuroepithelium is a source of renewal of olfactory receptor neurons, which have a powerful nourishing effect on the brain, and can be a direct source of additional cells for the brain. Scientists are now identifying the characteristics of these cells. These findings have profound implications for the repair and regeneration of the nervous system.

Anatomical and physiological damage to the olfactory system appears to occur early in the development of Alzheimer's and other serious neurological diseases. The etiology of deficits in olfaction and their predictive value as early warning signs of these diseases is being studied by NIDCD-supported investigators.

Scientists supported by the NIDCD have utilized the tools of molecular biology to uncover important information on how human communication systems work at a fundamental level. This is an area I intend to encourage for development and expansion. NIDCD scientists have uncovered important information on the molecular biology of cochlear outer hair cell motility which plays an important role in hearing by modulating the micromechanical properties of the hearing organ. These scientists have recently defined one of the mechanisms that regulates the movements of the outer hair cell. I believe the time is ripe to exploit also the particular opportunities that exist in molecular genetics. Scientists are moving closer to identifying the genes and their products responsible for hereditary deafness. This research holds the promise of genetic replacement and interrupting the aberrant process to prevent deafness.

Noise exposure represents the most common preventable cause of hearing loss today. The NIDCD sponsored a Consensus Development Conference on Noise and Hearing Loss at the NIH on January 22-24, 1990. The statement drafted by the conference panel provided recommendations and avenues for future research related to noise and hearing loss. Among the topics the Panel recommended for future research are investigations into the mechanisms underlying noise-induced hearing loss and the evaluation of the efficacy of hearing conservation programs. The NIDCD is planning a major public health educational program on the cause and prevention of noise induced hearing loss.

Half of our children have ear infections before they reach their first birthday, and nine out of 10 children have ear infections by the time they are 6 years old. Otitis media is the leading cause of acquired hearing loss before age 10. The NIDCD is collaborating with the NIAID and the NICHD in issuing a solicitation for research on a vaccine against otitis media.

Perilymphatic fistulas are fluid leaks through defects in one or both of the small windows between the middle and inner ears. The symptoms include dizziness, ringing in the ears, and hearing loss. Considerable controversy surrounds the diagnosis of perilymphatic fistula. The NIDCD will issue a Request for Applications (RFA) to study the differential diagnosis of perilymphatic fistula, seeking a diagnostic marker for perilymph fluid that would confirm the presence of a leak, as well as other clinical aspects of perilymphatic fistulas.

Congenital cytomegalovirus (CMV) is a well-established cause of disorders of the auditory, visual, and central nervous systems. New evidence suggests that "quiescent" CMV may play a role in the development of perilymphatic fistulas and Meniere's disease (a disorder that affects the inner ear and causes episodes of vertigo, fluctuating hearing loss, and a roaring sound in the ears). Other studies will focus on CMV in AIDS patients to determine whether the deafness and communication disorders often reported among those patients are due to the CMV or to the AIDS virus. The population that is particularly in need of study are the pediatric AIDS patients. The NIDCD will begin its support of research on the effect of AIDS in communication systems in FY 1991.

Millions of Americans age 17 and older have experienced a dizziness or balance problem. Several groups of people are particularly at risk for different reasons. A majority of people over 70 years of age report problems of dizziness and imbalance, and balance-related falls account for more than one-half of the accidental deaths in the elderly. The NIDCD is encouraging research aimed at improving our understanding of the causes, treatment, and prevention of these disorders that present safety and quality of life issues for elderly Americans. A new area of balance research has been generated by the space program. A number of research needs must be addressed in this area, including space motion sickness among astronauts during the early stages of the mission.

Institute-supported scientists have made great advances in therapeutic approaches to speech, voice, and language disorders. This year, investigators in the NIDCD intramural program were the first to demonstrate a successful treatment for voice tremor, which affects women primarily and makes speech difficult to understand. Scientists in the Speech and Voice Unit injected botulinum toxin into muscles of the voice box of patients with this disorder and successfully eliminated the tremor. Botulinum toxin injections have also proven to be effective in treating another voice disorder, spasmodic dysphonia, which has been treated by cutting one of the nerves to the larynx. In another exciting advance this year in our extramural program, a new treatment, photodynamic therapy, has been found to be effective for recurrent laryngeal papillomavirus infections. Other conventional and experimental therapies including vaccines and interferon failed to cure this disease. This represents a promising new therapy for a difficult to control and life-threatening disease.

An estimated 10 million Americans have taste and smell disorders. A predominant problem is the natural decline in smelling ability that typically occurs after age 60. Some people are born with chemosensory disorders, but most patients develop them after an injury or illness. Loss of the senses of smell and taste can also be caused by exposure to certain chemicals and by some medicines. A person with faulty senses of taste and smell is deprived of an early warning system that most of us take for granted. Smell and taste alert us to fires, poisonous fumes, leaking gas, and spoiled foods. In addition to a reduction in quality of life for those unable to smell or taste, the loss of these senses can be associated with nutritional deficiencies in the elderly. Interest in and enthusiasm for eating are much reduced in those who cannot smell or taste their food.

The NIDCD Intramural Research Program is a strong program that is widely recognized for its ground breaking research through basic and clinical studies. I hope to develop this program further to include units of excellence in each of our areas of science. I intend for our intramural program to provide a model to the scientific community in molecular biology and molecular genetics, to conduct clinical trials of promising new therapies and to serve as a national training resource.

Last year we reported to you on the Research Plan for the Institute -- the National Strategic Research Plan. This year we are analyzing our research grant portfolio relative to the Plan, looking for areas that need particular Institute emphasis. In addition, this year, we have a second Plan, one for training. There remains a shortage of trained investigators in our fields. In July 1989 the NIDCD convened a panel of expert consultants to identify critical research training activities that could be implemented by the NIDCD in three time periods: the next one to two years, five years from now, and 10 years from now. The report from this panel included a number of valuable and specific recommendations. We are implementing a number of these recommendations including establishment of a Physician Scientist Award. Special emphasis will be placed on research training of underrepresented minorities and communicatively-impaired individuals. We are developing a third plan for acquiring sound epidemiologic data in each of the areas within the NIDCD mission.

The NIDCD will initiate a new Centers program through two mechanisms. We plan to award National Multipurpose Research and Training Centers to support basic and clinical research, research training, continuing education for health professionals, and dissemination of information to the public. The NIDCD will use an innovative mechanism to widen the opportunity for more institutions to participate in the Centers program. This mechanism is the Exploratory Grants program, which encourages institutions with limited experience in multidisciplinary research to develop and test such a program.

The Institute has undertaken a number of activities toward the development of an information Clearinghouse, including a major, successful meeting in October 1989 that identified gaps in information as well as existing sources of information. The goal of this Clearinghouse is to be an Institute resource where the results of the latest studies funded by the NIDCD are made available to the lay public, researchers, professionals, and organizations.

In closing , I would note that we live in the information age. Never before has the ability to communicate effectively had such a major effect on the individual's economic and social well-being. The NIDCD is committed to excellence in research and to maximizing the benefits of research advances and making available the latest technology to Americans who would benefit most, the communicatively handicapped. The Institute will make every effort to ensure that the latest information from research is known to the afflicted, the public, medical professionals, and other scientists.

Mr. Chairman, the FY 1991 budget request is $122,847,000. I will be pleased to answer any questions you might have.

BIOGRAPHY OF DR. JAMES B. SNOW, JR.

Born: March 12, 1932, Oklahoma City, Oklahoma

Marital Status: Married, three children

Education: B.S., University of Oklahoma, Norman, Oklahoma, 1946-49;
M.D., Harvard Medical School, Boston, Massachusetts 1952-56.

Professional History: Intern in Surgery, Johns Hopkins Hospital, Baltimore, MD, 1956-57. Resident in Otolaryngology, Massachusetts Eye and Ear Infirmary, Boston, MA, 1957-60. U.S.P.H.S. Research Trainee, Massachusetts Eye and Ear Infirmary, Boston, MA, 1959-60. Captain, Consultant in Otolaryngology, 1960-61. U.S. Army Medical Corps, 8th U.S. Army, 121st Evacuation Hospital, Korea; Otolaryngologists, U.S. Army Hospital, Fort Leonard Wood, MO, 1961-62. Assistant Professor and Vice-Chairman, Department of Otorhinolaryngology, University of Oklahoma Medical Center, Oklahoma City, OK, 1962-64. Professor and Head, Department of Otorhinolaryngology, University of Oklahoma Medical Center, Oklahoma City, OK, 1964-72. Adjunct Professor, Department of Oral Medicine, University of Pennsylvania, School of Dental Medicine, 1974-1977. Professor and Chairman, Department of Otorhinolaryngology and Human Communications, University of Pennsylvania, School of Medicine, Philadelphia, PA., 1972-1989. Director, National Institute on Deafness d Other Communication Disorders, 1990 - .

Society Affiliations: Alpha Omega Alpha, American Academy of Facial Plastic and Reconstructive Surgery, American Academy of Otolaryngology-Head and Neck Surgery, American Association for the Advancement of Science, American Broncho-Esophagological Association, American College of Surgeons, American Laryngological Association, American Laryngological, Rhinological and Otological Society, American Medical Association, American Neurotology Society, American Otological Society, American Society for Head and Neck Surgery, Association of Academic Departments of Otolaryngology-Head and Neck Surgery, Association for Research in Otolaryngology, Association for Research in Otolaryngology, Association of American Medical Colleges, College of Physicians of Philadelphia, Collegium Oto-Rhino-Laryngologicum Amicitiae Sacrum, International Bronchoesophagological Society, John Morgan Society, Massachusetts Eye and Ear Infirmary Alumni Association, New York Academy of Sciences, Pan American Association of Otolaryngology and Broncho-Esophagology, Pennsylvania Academy of Ophthalmology and Otolaryngology, Pennsylvania Medical Society, Phi Beta Kappa, Philadelphia Bronchoscopic Club, Philadelphia County Medical Society, Philadelphia Laryngological Society, Sigma Xi, Society for Ear, Nose and Throat Advances in Children, Society of University Otolaryngologists-Head and Neck Surgeons, Southern Medical Association.

Honors and Awards: Reagents' Award for Superior Teaching, University of Oklahoma, 1970. Certificate of Award, American Academy of Ophthalmology and Otolaryngology, 1971. Honorary Master of Arts, University of Pennsylvania, 1973. Second Vice President, American Academy of Ophthalmology and Otolaryngology, 1973-74. Consulting Professor, Shanghai Second University of Medical Sciences, Shanghai, People's Republic of China, 85. Honorary Fellow, Japan Broncho-Esophagological Society, 1985.

REMARKS OF DR. JAY MOSKOWITZ

Senator HARKIN. Dr. Moskowitz, did you have anything you want to add to that at all?

Dr. MOSKOWITZ. I just wanted to thank you for your very generous remarks and say that the efficient establishment of this Institute was a joint effort by the representatives of the more than 30 million people affected by the disorders within the purview of the Institute, and the 500 researchers who were quick to answer any request that we had during the year and a half. Each has helped to establish what we think will be a very valuable institute.

Senator **Harkin**. Thank you very much, and my personal thanks to you for shepherding this Institute through its first year.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

ADEQUATE SPACE

Question. Do you currently have adequate space to get an intramural research program up and running and to have adequate office space and clinical space in the Warren G. Magnuson Building?

Answer. We have negotiated plans with the NIH Division of Space Management for existing and future requirements for the Office of the Director; Extramural Programs; and Intramural Research, including clinical programs. At this time, the plans are quite satisfactory. If we can occupy the space within the scheduled timeframe, it will satisfy our immediate requirements.

RESEARCH TRAINING

Question. Specifically, how many researchers do you think would be optimum, and is the training budget request adequate to meet this level?

Answer. The training budget request will allow the Institute to maintain its current level of research training whereby each trainee or fellow receives two years of training support. Data from two NIH studies (1982, 1987) and a Training Task Force Report (October, 1989) show that researchers trained for two years and more are more likely to apply for and be awarded research grants. NIDCD plans to encourage all recipients of training awards to commit to at least two years of research training and three years when possible.

Question. How do you plan to address the shortage of trained investigators in the fields of science in your area?

Answer. A short- and long-range training plan was developed last year by a group of advisors to the Institute. They made a number of recommendations which will be implemented over the next 2 to 10 years. High on their list of priorities is the need to increase the flow of graduate students who select careers dedicated to clinical and basic research in hearing and other communication disorders. One recommendation is to permit appointment of more predoctoral candidates on the traditional Institutional NRSA Training Grants. The second is to award funds to ten proven, enthusiastic, NIDCD-supported investigators to plan and present undergraduate survey courses on communication sciences and disorders at four-year, non-research colleges to junior- and senior-level students. Data show that many career decisions are made at this time. The third means of increasing the pool of predoctoral students is the implementation of a type of "mentor award," whereby a selected number of NIDCD-supported investigators receive support to bring a predoctoral student into his/her laboratory to gain "hands-on" research experience. The three approaches to increasing the pool of predoctoral students in NIDCD-mission oriented sciences also are intended to be used heavily to increase the number of underrepresented-minorities and communicatively-handicapped students who will eventually be candidates for post-doctoral research training.

APPLIED RESEARCH

Question. Dr. Snow, what is your view with regard to the appropriate mix between basic and applied research. As you know, there is a great deal which can be done to assist people with communication disorders based on current information. What priority will you place on applied research that can more directly and more immediately bring assistance to individuals with communication disorders?

Answer. The NIDCD is currently supporting research across the entire biomedical spectrum -- from basic research to applied clinical trials and prevention and rehabilitation. I consider each component of the spectrum to be of critical importance. Progress in biomedical research includes many stories where basic studies have uncovered important information related to clinical problems and where clinical studies have stimulated important investigations related to basic mechanisms. As we build on the science foundation that has been established in the Institute, I think it is vitally important that basic and applied research both continue to grow and that we keep open the lines of communication and collaboration between scientists in all dimensions of research.

MOLECULAR BIOLOGY

Question. A strategy for the Institute (The National Strategic Research Plan) was suggested by a task force of leaders in the communication field recommending that a high priority for research be the application of tools of molecular biology to improve vaccines for young children (2 1/2 years and below) whose immune systems are not mature enough to respond to current vaccines. Is this initiative adequately supported by your fiscal year 1991 request?

Answer. Current plans are to provide up to 1.5 million dollars total direct costs per year for a project period of five years. The FY 1991 request provides for continued support of this clinical trial and otitis media research centers in Minnesota, Massachusetts, Ohio, and Pennsylvania, where studies related to otitis media vaccines are presently conducted.

CLINICAL TRIALS

Question. What clinical trials would you like to begin? Will you have funds to initiate any new clinical trials?

Answer. There are several clinical trials that are in the planning process:

Drug Treatment of Tinnitus: Preliminary studies in two laboratories have indicated that a particular calcium channel blocker may have some usefulness in reducing or alleviating tinnitus. A clinical trial could test nifedipine, as well as two other licensed drugs, an anticonvulsant and a vasodilator, which have shown some promise as well. Identifying a drug effective against tinnitus would make a major impact on millions of tinnitus sufferers.

Prevention of Central Auditory Changes Related to Peripheral Hearing Loss: An NIDCD-supported scientist was the first to identify and describe morphological changes in the cochlear nucleus secondary to conductive and sensorineural hearing impairment in mice. More recent work has indicated that a specific ganglioside, administered at the beginning of hearing loss, prevents the characteristic central morphologic changes that appear in untreated experimental animals with the same hearing loss. Another set of studies have shown that chronic extracochlear low amplitude electrical current has the same effect of reducing or eliminating central morphological changes in deafened animals. These studies should be supported vigorously, as the implications for children deafened in early infancy or childhood are far-reaching.

Reduction of Susceptibility to Noise-induced Hearing Loss: Preliminary studies suggest that susceptibility to noise-induced hearing loss, the most common preventable cause of hearing loss, can be reduced by a substance called biotin, which has the same action as aspirin.

Use of Steriods and Surgery for Treatment of Olfactory Defects: A clinical trial of steroids and/or surgery for the diagnosis and treatment of correctable causes of certain smell disorders would utilize objective chemosensory, rhinological, and other medical measurements.

Predictive Efficiency of Intraoperative Cranial Nerve Monitoring: Cranial nerve monitoring has been used by neurosurgeons and neurotologists for almost 10 years. There is no general agreement, however, as to the predictive efficiency of the technique. Follow-up studies have ranged from questioning the patient about his or her postoperative hearing status on the telephone to extensive batteries of auditory and vestibular tests. Systematic studies should be completed which consider patient variables, surgical variables, and recording variables in order to create a data-based set of criteria for what constitutes a significant intraoperative change; and to identify the sensitivity, specificity, and test efficiency of ABR to identify permanent changes in peripheral or central auditory function.

The President's Budget does not include funds for these trials.

GENETICS RESEARCH

Question. What progress can you report in genetics research?

Answer. Scientists supported by the NIDCD have reported progress in a number of studies related to genetics research. Examples include information acquired in studies of families with language impairment. Researchers have learned more about the basis of language impairment in children through studies of the contribution of genetic factors. Families of language-impaired children were found to be significantly more likely to report a history of impairment in other family members, with higher rates of affected siblings and parents.

Usher's syndrome, characterized by congenital deafness, progressive visual impairment leading to blindness, and, often, mental retardation, may account for as much as 10 percent of all congenital deafness. In a significant advance in this field, NIDCD researchers have recently located the Usher's gene on chromosome 1. Investigators are pursuing this finding and information learned can be used to improve diagnosis and genetic counseling and may eventually lead to gene therapy.

Finally, NIDCD intramural researchers are continuing their internationally-recognized studies of the genetics of deafness. Genetic factors are known to cause more than 50 percent of all cases of severe childhood deafness. These scientists are using recently developed molecular biology and genetic techniques to map the genes whose mutations cause hearing impairments. The focus for these genetic studies in the NIDCD intramural program is on mapping the gene for Waardenburg's syndrome. The mutation of one single gene is the most likely cause of this hereditary disorders, which has hearing imapirment as a component. The NIDCD intends to expand its genetics studies intramurally with the creation of a new Laboratory of Molecular Genetics whose goal is to study the genetic factors related to deafness, hearing impairment, and voice, speech, language, olfactory, gustatory and vestibular disorders.

NEW TREATMENT FOR PAPILLOMAVIRUS INFECTIONS

Question. Can you explain a little more about the new therapy for papillomavirus infections of the larynx? What benefits does it provide for patients with these infections?

Answer. Yes. Papillomavirus infections of the larynx and upper respiratory tract are a serious disease which can cause a life-threatening obstruction of the respiratory tract. Patients with this infection develop multiple folds that appear as warts. Previously, they were treated by surgical removal. This was not a satisfactory method, as scarring often developed. A variety of other conventional and experimental therapies were tried, but also failed to cure this disease. A new treatment is now available and I consider it to be a real advance in this field and a genuine benefit to patients with papillomavirus infections. Photodynamic therapy has been demonstrated to be quite effective in treating upper respiratory tract recurrent papillomavirus infections, eliminating the need for surgery. This represents a new and creative therapy for a difficult and clinically-frustrating disease.

BOTULINUM TOXIN TREATMENT FOR SPEECH AND VOICE DISORDERS

Question. Can you give us more information on the use of botulinum toxin injections for speech and voice disorders?

Answer. Patients with many different types of speech disorders have overly-active or spasmodic muscles which disrupt speech and voice production. These include: spasmodic or spastic dysphonia; voice tremor, oromandibular dystonia or dyskinesia, and stuttering. The NIDCD Division of Intramural Research was the first to demonstrate significant speech improvements in spasmodic dysphonia after injecting botulinum toxin into one vocal cord. Since then a complete double-blind clinical trial has been completed demonstrating an improvement in 90 percent of patients, many of whom had a normal voice for two to three months following injection.

Botulinum toxin does not directly affect either the nerve or the muscle but rather disrupts communication between the two, resulting in beneficial muscle weakening and reduction of spasms. This weakness continues for three to four months after which there is sprouting at the nerve terminal with muscle reactivation and symptom recurrence. At that time the muscles can be re-injected and the symptom can again be relieved. Of the 100 patients treated over the last four years, 85 percent continue to get symptom relief following repeated injection. This treatment is similarly effective in treating voice tremor for which there is no other treatment available.

The NIDCD has also been using this injection technique in stutterers. At first, only the muscles in the voice box or larynx were injected, which helped reduce stuttering but also reduced speech volume. Now, since other muscles seemed to be involved in some stutterers, injections are being given in other muscles including the lips and jaw which may reduce stuttering without reducing speech volume. Although the effects on stuttering are not as dramatic as in spasmodic dysphonia, the results are telling us a great deal about the disorder and the role of muscle action feedback in stuttering behavior.

Botulinum toxin muscle injection has also been used successfully in oromandibular dystonia, a disorder with uncontrolled spasms of the jaw, lip or tongue muscles. This problem is one of constant over contraction of the speech muscles. In the first 20 patients, 16 patients or 85 percent have had significant improvement.

Finally, a small subgroup of patients, some with spasmodic dysphonia and others with oromandibular dystonia, have had a permanent benefit; they have not needed any further treatment for at least two years since injection. The long term benefits of this treatment in these four speech and voice disorders will continue to be studied by the NIDCD.

CONSENSUS DEVELOPMENT CONFERENCE ON NOISE

Question. What did you learn in your recent consensus development conference on noise?

Answer. Exposure to loud sounds at any age can cause damage to the sensitive structures of the inner ear. This damage may produce temporary or permanent hearing loss that is not reversible by available medical or surgical treatment. In the United States, it is estimated that over 10 million people of the 28 million with hearing impairments sustained the damage from exposure to loud sounds. This statistic is staggering since hearing damage by noise exposure is preventable.

The Consensus Panel concluded that sounds of sufficiently high intensity and long duration will damage the ear and result in temporary or permanent hearing loss at any age. The effect of repeated sound overstimulation is cumulative over a lifetime and not currently treatable. Injury to the inner ear from noise exposure usually does not cause pain. Tinnitus or ringing in the ear, a muffling of sounds heard, or a feeling of the ears being plugged up are some of the symptoms experienced after exposure to damaging noise.

Two types of noise injury are recognized: noise-induced hearing loss and acoustic trauma. Noise-induced hearing loss results from prolonged exposure to intense noise. Acoustic trauma results from short-duration, very intense sounds like an explosion which may cause an immediate, severe, and permanent hearing loss. Repeated exposure to sounds that cause temporary hearing loss may gradually cause permanent noise-induced hearing loss. In this type of injury, the cochlear blood flow may be impaired, and a few hair cells are damaged with each exposure. With continued exposure, the number of damaged hair cells increases. Once destroyed, the sensory cells cannot be replaced. For some forms of exposure, a recovery period allows damaged regions of the inner ear to heal, creating scar formation. If this healing process does not occur, the hair cells and eventually the nerve fibers in the region continue to degenerate.

Susceptibility to noise damage varies greatly among individuals. The panel determined that current scientific knowledge is inadequate to predict which individual will be relatively more susceptible when exposed to a hazardous sound. Some antibiotics and chemotherapeutic agents have appeared to facilitate the damaging effects of noise exposure, and precautions should be taken with regard to noise exposure for patients being treated with these medications.

The Consensus Panel recommended that government regulations of noise levels should be revised to encompass all industries and be strictly enforced. Model community ordinances, high-visibility media campaigns, and manufacturer incentives to design quieter industrial equipment and consumer goods are among the panel's other recommendations.

PROFESSIONAL JUDGMENT BUDGET

Question. Dr Snow, for the record would you tell the Committee what your professional judgment budget is for your Institute in fiscal year 1991.

Answer. The FY 1991 professional judgment budget for the National Institute on Deafness and Other Communication Disorders is $161,632,000.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

RESEARCH TRAINING

Question. Dr. Snow, I understand the Institute convened a panel of experts to recommend a strategy for increasing the number of researchers in the field of communication disorders. Has the panel completed its work? What were the recommendations?

Answer. The National Strategic Research Plan provided a blueprint for research studies and served to stimulate increased research efforts in all areas within the mission of the NIDCD. However, the NIDCD has targeted research training for specific emphasis since there is a critical need to train scientists to undertake the many research studies that have been identified. New investigators must be trained and established investigators who are currently engaged in research in related areas must be encouraged to bring their skills and expertise to communication sciences and disorders. An independent panel on training met in July 1989 and provided a number of recommendations for addressing the shortage of researchers in our areas, including predoctoral students, postdoctoral fellows, and experienced investigators. Recommendations that will be pursued by the NIDCD include the initiation of the Physician Scientist Award, the Mentor Award, and the Small Grant Programs. We are emphasizing the training of minority individuals and communicatively-impaired individuals in these training programs.

Question. To what extent does the Institute's FY 91 budget reflect the panel's recommendations? How much would be necessary to fully implement the panel's short-term recommendations?

Answer. The NIDCD is planning to implement several of the short-term recommendations suggested by the panel. One of the short-term goals is to emphasize the number of predoctoral trainees on Institutional NRSA grants. Other short term recommendations are the support of conference grants to permit attendance of predoctoral students at national research meetings, develop seminars to be presented by NIDCD staff and investigators in "grantsmanship," initiate small grant program for pilot and high-risk research projects, create a "mentor award program" by providing supplements to current principal investigators for training of quality candidates with doctoral degrees, and increase utilization of the short-term (T-35) training program on Institutional NRSAs. The NIDCD is evaluating some of the other recommendations of the panel on training to determine how to implement them into the NIDCD training program.

RESEARCH CENTERS

Question. Dr. Snow, I note in your written statement that the Institute's new Centers Program will initiate an "Exploratory Grants" program. How will this differ from the existing centers program?

Answer. The Exploratory Grants program will enable institutions with limited experience in setting up multidisciplinary research programs an opportunity to develop such a program and test it. The awarding of an Exploratory Grant will allow the development and strengthening of the research program of the institution and may enable that institution to compete successfully for a multipurpose center grant.

Question. How many exploratory grants do you intend to award in FY 90 and in FY 91? What do you anticipate will be the average cost of each grant? How does this compare with the other center grants?

Answer. The Exploratory Grants Program is a new initiative in FY 1991. The budget request will allow the Institute to support approximately three Exploratory Centers at an average cost of $249,000. The anticipated average cost of the NIDCD Comprehensive Centers is $800,000; and the estimated cost of a Multipurpose Research and Training Center is $1,500,000.

QUESTIONS SUBMITTED BY SENATOR WARREN RUDMAN

RESEARCH ON STUTTERING

Question. An estimated 14 million children and adults in the United States suffer from speech and language disorders, the most common of which is stuttering. Your budget justification links such disorders to a variety of factors, including neurological abnormalities. Researchers at the Dallas Center for Vocal Motor Control, the University of Texas Southwestern Medical School and the Collier Center for Communication Disorders have used magnetic resonance imaging technology to identify neurological irregularities in individuals who stutter or suffer from spasmodic dysphonia and have identified subtle irregularities in electrical activity and blood flow in the brains of 60 percent of stutters whose speech is broken by abnormal pauses, repetitions or prolongations of sounds. It is my understanding that the Institute has recently terminated funding for the research project at the Center for Vocal Motor Control, despite the fact that a year ago when asked what NIDCD was doing to understand stuttering, this research was among the projects cited. What was the basis for the decision to terminate funding?

Answer. The research project at the Dallas Center for Vocal Motor Control (CVMC) was funded from 1983-1989. The most recent application from CVMC was judged by a panel of scientists to have sufficient technical and scientific flaws to warrant a poor score and the weight of the criticisms was such that funding could not be renewed. However, the researchers have been encouraged to revise and reorganize their research plan with the aim of proposing a fundable project. The Institute has a strong commitment to support research in stuttering and spasmodic dysphonia, the areas addressed by CVMC. Nonetheless, every effort must be taken to ensure that research which is supported is of the highest quality. The NIH review process has long proven the most effective means of determining and ensuring that quality.

Question. In an appeal to the NIDCD Council, the Center for Vocal Motor Control has raised a number of issues concerning the review process used in evaluating its research proposal (see attached). I would appreciate your response to the issues raised by Drs. Finitzo and Freeman concerning the review process.

Answer. The initial review of the Center for Vocal Motor Control (CVMC) research proposal was conducted by a study section of the Division of Research Grants (DRG), NIH. The principal investigator was dissatisfied with the outcome of that initial review and took advantage of a process available to all applicants and submitted a letter of rebuttal, which requested reconsideration of the application. The letter was reviewed by staff and the NIDCD Council along with the grant application. Following this review, the NIDCD Council concurred with the recommendations of the initial review group.

Question. What is your institute doing to support research of the type currently underway at the Center for Vocal Motor Control? Are you currently funding any research projects in the area of basic brain research?

Answer. Current support in stuttering includes two Academic Research Enhancement Awards, two individual research projects and portions of several individual and program project grants. Program staff continue to actively solicit and encourage research applications focused on stuttering. A recently issued Program Announcement has resulted in an increased number of applications focused on this topic. If these fare well upon review, increased dollar support for stuttering research could result. Within the Intramural portion of NIDCD, major efforts are underway to understand the pathophysiology of spasmodic dysphonia, and to employ new treatment approaches for this debilitating voice disorder. The Institute is funding numerous projects in basic brain research, which also relate to speech and voice disorders.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

STATEMENT OF DR. RUTH L. KIRSCHSTEIN, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Dr. Kirschstein, welcome to the committee. Your Institute of General Medical Sciences conducts important underlying research, assisting all the other Institutes in their work.

Of course, one of my special interests is the human genome project and I want to ask you some questions about that. Now let us see, your request is for $745.49 million, or a 4.7-percent increase.

Welcome again and please proceed.

Dr. KIRSCHSTEIN. Thank you, Mr. Chairman. This year it is a particular pleasure for me to tell you about the accomplishments of the basic biomedical research programs of the National Institute of General Medical Sciences. As so often before, our Institute has been awarded two of the world's most prestigious biomedical research prizes.

The 1989 Nobel Prize in chemistry was awarded to Drs. Thomas Cech of the University of Colorado at Boulder and Sidney Altman of Yale University. I might tell you, Mr. Chairman, that Dr. Cech is a graduate of Grinnell College, Iowa.

The second award, the Lasker Award in basic medical research was shared with three others by Dr. Alfred Gilman of the University of Texas Southwestern Medical Center.

The discoveries of Drs. Cech, Altman and Gilman signify the coming together of the fundamental research endeavors in chemistry and biology that are the hallmarks of NIGMS-supported studies, and are of great importance to improving, not only the well-being of the people of the United States, but also the economic well-being and the competitive status of this country in world markets.

RNA

The revolutionary discovery by Drs. Cech and Altman that ribonucleic acid, RNA, long thought only to carry genetic messages, can also act as a biochemical catalyst, has led, in the space of 8 years, to the possibility of very important practical applications.

For example, attempts are underway to develop this technique as a means of blocking the activity of the human immunodeficiency or AIDS virus.

But, in continuing these basic biomedical research endeavors, we must prepare for the future, and the United States must be cognizant of the economic and demographic imperative, namely, that by the year 2000, one-third of the new entrants into the work force, including biomedical researchers, will be minorities.

The NIGMS now has a unique opportunity to help ensure that there will be a group of well-prepared minority biomedical researchers, since in fiscal year 1990, both the minority access to research careers [MARC] and the minority biomedical research support [MBRS] programs will be residing in this Institute and we will be able to coordinate those efforts.

But NIGMS also has a critical role in research training generally, particularly through its highly successful Medical Scientist Training Program, the combined M.D.-Ph.D. degree granting program.

Furthermore, the rapidly growing biotechnology industry in the future will continue to rely on the work of well-trained scientists, and our recently begun NIGMS biotechnology research training program can be expected to play an increasingly vital role in the continued commercialization of important scientific discoveries.

PREPARED STATEMENT

On the basis of these activities and the continued training of new, young scientists to do research, I am confident that the quality of NIGMS-supported basic research in the future will be even better than the superb scientific achievements that I have talked about today.

The budget request for fiscal year 1991 is $745,494,000, and I would be pleased to answer any questions you may have.

[The statement follows:]

STATEMENT OF DR. RUTH L. KIRSCHSTEIN

It is an honor for me to appear again before this committee, to present the outstanding programs and accomplishments of the National Institute of General Medical Sciences (NIGMS). This year, it is a particular pleasure to tell you that, as so often in past years, two of the most prestigious biomedical research prizes have been awarded to NIGMS grantees. The 1989 Nobel Prize in chemistry was awarded to Drs. Thomas Cech of the University of Colorado at Boulder and Sidney Altman of Yale University and the 1989 Lasker Award for Basic Medical Research was shared, with three others, by Dr. Alfred Gilman of the University of Texas Southwestern Medical Center.

The discovery, by Drs. Cech and Altman, that ribonucleic acid (RNA), long thought only to carry genetic messages, can also act as a biochemical catalyst, or enzyme, came as a complete surprise. This revolutionary finding has led to the coining of a new term in biology, "ribozyme" or RNA enzyme. Ribozymes are not just curiosities of nature. In just eight years since their discovery, scientists are already thinking of some very important practical applications. Indeed, a number of university laboratories and biotechnology companies now are making what are being called "designer ribozymes," RNA enzymes tailored to catalyze very specific reactions. For example, attempts are underway to develop a ribozyme designed to block the activity of the human immunodeficiency or AIDS virus.

Dr. Alfred Gilman of the Department of Pharmacology, University of Texas, Southwestern Medical Center, the recipient of the Lasker Award, discovered a family of proteins known as the G proteins. G proteins have been recognized to be integral to the transmission of signals into and within cells. If there is disruption of G protein activity, cells malfunction and several specific diseases may result. For example, the toxin produced by the bacteria that cause pertussis is known to act by disrupting the binding of one of the G proteins to the cells of the lungs, thereby causing the symptoms we all recognize as whooping cough. A different toxin, produced by the cholera bacteria, results in the persistent, abnormal activation of another G protein in the cells lining the intestinal tract, causing the tremendous loss of fluid in that disease, a loss which can lead to prostration and, often, death. Abnormalities of G proteins have also been implicated in some forms of cancer.

This remarkable work combines physiology, pharmacology, molecular biology and, again, chemistry. Dr. Gilman's broad background and training enabled him to move from discipline to discipline as the scientific opportunities arose. He has a combined M.D.-Ph.D. degree from Case-Western Reserve Medical School in a program that was a predecessor to the highly successful Medical Scientist Training Program now funded by NIGMS. Dr. Gilman was a graduate of the small, but outstanding, NIGMS intramural research training activity, the Pharmacology Research Associate Training Program. We have just learned that he will also be the 1990 recipient of the highly regarded Passano Award.

The enormous significance to the field of biomedical research of these two discoveries, RNA enzymes and G proteins, is obvious. Together they signify the congruence and melding of the fundamental, undifferentiated research endeavors that are the hallmarks of support of the National Institute of General Medical Sciences. This "coming together" of the basic research areas of biology and chemistry is of great importance to improving not only the well-being of the people of the United States, but also of the economic and competitive status of this country in world markets.

Another important example of the "coming together" of synthetic chemistry and biology is the work of Dr. E. J. Corey of Harvard University, a long-time NIGMS grantee, who has coined another new term, "chemzymes," for the unique synthetic catalysts or enzymes that he has developed. These chemzymes are small, totally synthetic molecules, whose design is based on a rational analysis of molecular structure. These designer chemzymes can distinguish molecules in a solution as being either "left-handed" or "right-handed" and choose the one to which the fit is best, like a left-hand glove which will only fit on a left hand. This ability to selectively recognize only the active molecules makes the action of chemzymes extremely efficient. A chemzyme, for example, can be tailor-made to facilitate binding of a drug to a virally infected cell. As might be expected, pharmaceutical manufacturers have quickly developed collaborations with the Harvard chemists. Important new therapeutic entities now are being developed using this approach to rational chemical synthesis.

The combined techniques of molecular biology, chemistry and strctural biology are being used to identify and characterize the subunits of the cell, each of which is essential to its normal functioning. Of particular importance is the cell's surface membrane which basically serves to confine the contents of the cell, allow intercellular communication and permit messages to enter or leave the cell. Some cells have special receptor molecules in their surface membranes. For example, the cells that line blood vessels have receptors or "adhesion molecules" which allow circulating white blood cells, such as lymphocytes, to adhere to the vessel lining, migrate through the vessel wall and then seek out inflamed or injured tissues. In some cases, this permits the control of infections. In others, burn injuries may more rapidly heal because these white blood cells are able to reach the burned tissue rapidly and allow the repair process to begin. The work of NIGMS grantees in the biochemical identification and characterization of these adhesion molecules has enormous implications for the prevention of the spread of cancer cells, for the treatment of cancers that already have spread, and for the design of therapeutic substances that can be targeted to diseased tissues.

In another area of research, biophysics, I would note that the Institute's grantees have made excellent progress in elucidating the three-dimensional structures of a number of biologically important proteins and other macromolecules. This year, biophysicists, working with support from NIGMS, have begun to make significant advances in determining the specific three-dimensional structures of some of the proteins important to the activity of the human immunodeficiency virus. These advances have enabled other scientists to begin to design chemicals or drugs which take advantage of the structural features to inhibit AIDS infection. This line of attack against this dread viral infection, like those I mentioned earlier, again illustrates the intersection of the chemical and pharmacological sciences with the physical sciences, and molecular biology.

As the chemical, physical and biological sciences become more and more interactive, the need for extremely well-prepared researchers in a wide range of areas is more and more apparent. The NIGMS research training programs have long stressed interdisciplinary preparation of new young scientists. Leading researchers like Drs. Cech, Altman, Gilman, and Corey, are deeply involved in training such young people for future careers in research. While many of the remarkable advances which I have described herald the possibility of devising new strategies for diagnosis and therapy, they also raise a host of new questions which still must be addressed. To find the answers, this country needs a constant influx of skilled new research talent. The multidisciplinary research training programs of NIGMS are essential in the preparation of such highly qualified scientists, the very life-blood of future biomedical research progress.

But, in preparing for the future, the United States must be cognizant of the economic and demographic imperatives, namely, that, by the year 2000, one-third of the new entrants into the work force, including biomedical researchers, will be minorities. The NIGMS now has a unique opportunity to help assure that there will be a group of well-prepared minority biomedical researchers. With the beginning of Fiscal Year 1990, both the Minority Access to Research Careers (MARC) and the Minority Biomedical Research Support (MBRS) Programs reside in this Institute. Thus, NIGMS has the primary responsibility at NIH for such activities. Recognizing the importance of this responsibility, we have begun the process of improving coordination between the two programs, while keeping their distinct goals intact. During the past year, we had extremely successful meetings of the directors, the faculty and the students of each of the two programs. Dr. Louis Sullivan, Secretary of the Department of Health and Human Services, spoke at these meetings, serving as a role model and a source of inspiration to the students and their preceptors. In addition, the NIGMS is now supporting 24 minority undergraduate and graduate students, using administrative supplements to regular research grants to provide for their research training. All these efforts, along with a possible extension of the MARC Program to include honors students in the beginning years of college, indicate our commitment to the future role of minority biomedical researchers.

In addition, there are other essential areas of research training in which NIGMS has a critical role. For example, the need for physician-researchers throughout the United States makes the highly successful Medical Scientist Training Program, the combined M.D.-Ph.D. degree granting program, one of increasing importance. The example of Dr. Gilman's success as a pre-eminent physician-researcher is an inspiration to trainees in this program.

The rapidly growing biotechnology industry, in the future, will continue to rely on the work of well-trained scientists, like Drs. Gilman, Altman, Cech, and Corey, for the basic biomedical research discoveries that permit the production of important vaccines, antitoxins, drugs, and chemicals to treat and diagnose the diseases that still afflict mankind. This is why the recently started NIGMS biotechnology research training program can be expected to play an increasingly vital role in the continued commercialization of important scientific discoveries.

Clearly, the non-targeted research supported by NIGMS has opened up new vistas and produced new theories and concepts, but it also has had remarkable success in leading to new diagnostic and therapeutic opportunities. The challenges of uncovering the secrets of life and of elucidating the underlying causes of the still numerous diseases of man that are not yet understood are very great indeed. On the basis of current progress and with the continued training of new young scientists to do research, I am confident that the quality of the NIGMS-supported basic research of the future will be even better than the superb scientific achievements that I have presented to you today.

Mr. Chairman, the FY 1991 budget request for the Institute's research and research training programs is $745,494,000. I would be pleased to answer any questions you may have.

BIOGRAPHY OF DR. RUTH L. KIRSCHSTEIN

October 12, 1926. Brooklyn, New York

Education: A.B., magna cum laude, Long Island University, 1947. M.D., Tulane University School of Medicine, 1951.

Professional History: 1951-52, Internship, Medicine and Surgery, Kings County Hospital, Brooklyn, N.Y. 1952, Assistant Resident, Pathology, Veterans Administration Hospital, Chamblee, GA. 1952-54, Resident, Pathology, Providence Hospital, Detroit, MI. 1954-55, Trainee of National Heart Institute and Instructor in Pathology, Tulane University School of Medicine. 1956-57, Medical Officer, Resident in Pathology, Clinical Pathology, Clinical Center, NIH. 1957, Medical Specialty Board Certification, Pathology (anatomic and clinical pathology). 1957-60, Medical Officer, Pathologist, Laboratory of Viral Products, DBS, NIH. 1960-62, Chief, Section of Pathology, Laboratory of Viral Immunology, DBS, NIH. 1962-64, Assistant Chief, Laboratory of Viral Immunology and Chief, Section of Pathology, DBS, NIH. 1964-65, Acting Chief, Laboratory of Pathology, DBS, NIH. 1965-72, Chief, Laboratory of Pathology, DBS, NIH. 1971-72, Assistant Director, Division of Biologics Standards, NIH. 1972-73, Acting Deputy Director, Bureau of Biologics, FDA. 1973-74, Deputy Associate Commissioner for Science, FDA. 1974-present, Director, National Institute of General Medical Sciences, NIH.

Professional Organizations: American Association of Immunologists; American Association of Pathologists; American Society for Microbiology; Institute of Medicine, National Academy of Sciences.

Committee Memberships: Invited member of World Health Organization Expert Group on International Requirements for Biological Substances; Geneva, Switzerland, 1965 & 1971. Chairperson, NIH Grants Peer Review Study Team, 1975-76. Chairperson, PHS Genetics Coordinating Committee, 1976-79. Member, Fogarty International Center Scholars-in-Residence Advisory Committee, 1977-82. Chairperson, PHS Task Force on Women's Health Issues, 1983-84. Chairperson, PHS Coordinating Committee on Women's Health Issues, 1984-present. Member, NIH Advisory Committee for the IOM Study of the Organizational Structure of the NIH, 1983-84. Member, NIH Peer Review Committee, 1987-88. Member, HHS Executive Development Board, 1985-present. Member, Federal Task Force on Women, Minorities and the Handicapped in Science and Technology, 1987-present.

Honors, Awards: Elected to Institute of Medicine, National Academy of Sciences, 1982. Doctor of Science, Honoris Causa, The Mount Sinai School of Medicine, 1984. Honorary Doctor of Laws, Atlanta University, 1985. Presidential Meritorious Executive Rank Award, 1980. PHS Equal Opportunity Achievement Award, 1983. PHS Special Recognition Award--group award to PHS Task Force on Women's Health Issues (Chairperson), 1985. Distinguished Executive Service Award of the Senior Executive Association, 1985. Presidential Distinguished Executive Rank Award, 1985. Honorary Doctor of Science, Medical College of Ohio, 1986.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Dr. Kirschstein, thank you very much. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Biotechnology Industry

Question. As you know, America's leading biotechnology firm, Genentech, was just purchased by the Swiss. This Committee has been concerned for a number of years that the United States may get shut out of this emerging new industry.

How do you assess the sale of Genentech to the Swiss?

Answer. I have been one of many who has articulated concern that this country might lose its competitive edge in the field of biotechnology. Indeed, the sale of Genentech to the Swiss has caused some analysts to predict that "the nation could lose its dominance in another technology it pioneered." However, I do want to note that there are tremendous costs associated with bringing new products of biotechnology to market. Anywhere from $150 million to $250 million is required for a single drug, for example. The sale of Genentech is reputed to offer that firm the capital necessary to fully develop its products and, apparently, freedom to operate as an independent subsidiary of Roche, which is the owner of the drug firm, Hoffman-LaRoche.

Efforts to protect and foster the field of biotechnology are essential. Biotechnology research has provided us with the ability to produce, for example, human growth hormone, which is used to treat children who are abnormally short because their bodies do not make enough of this hormone. Tissue plasminogen activator, or TPA, is another product of biotechnology; TPA has saved countless heart attack victims by its ability to dissolve blood clots. The newest product is erythropoietin, now available to treat the serious anemia of patients in kidney dialysis.

New products are in need of further development, including one that may be used to treat AIDS. Without sufficient capital, these products may not be developed and commercialized. The sale of Genentech may be one means by which biotechnology research can be expedited to its full application for the diagnosis, prevention, and treatment of numerous diseases and disorders. It should not be viewed, however, as the only means, if we, as a Nation, can marshall our resources to help the industry fulfill its obvious promise.

Research Training

Question. Dr. Kirschstein, your Institute is clearly the focal point at NIH for research training, as you provide approximately two-thirds of the training slots for predoctoral trainees. Last year, the National Science Foundation issued a report which projected a nationwide shortage of 400,000 scientists as we enter the 21st century. This year, the National Academy of Sciences (NAS) has issued a similar report.

Could you tell us about that report and its findings and give the Committee your views as to what the research training needs are for FY 1991, and also for the decade of the 90's.

Answer. The Institute of Medicine/National Academy of Sciences' (IOM/NAS) report was issued by the Committee on Biomedical and Behavioral Research Personnel, which operates under the National Research Council. Some key findings contained in the report, which pertain to the need for biomedical research scientists and clinical investigators, include the following:

- The demand (job openings) for biomedical scientists has been growing relative to the supply of persons having the Ph.D. degree since the early 1980's.
- Growth in industrial employment is more than twice the rate of growth in academic employment.
- The percentage of M.D.s who are principal investigators on NIH research grants has fallen, although the number of M.D. principal investigators has remained fairly constant over the past decade.
- Unless the demand for biomedical researchers falls considerably from historical levels and/or enrollments and the production of Ph.D.s increases dramatically, it is projected that an undersupply of biomedical Ph.D. scientists will continue into the next century.
- For physician-scientists, the demand may be expected to increase as national R&D expenditures for health increase.
- Based on the results of a survey, many biotechnology firms are having problems hiring scientists. Over one-third report having labor shortages the past year.
- Over 80 percent of the biotechnology firms surveyed plan to maintain or increase current levels of hiring, particularly of individuals with postdoctoral research training.
- The IOM/NAS Committee recommends a 41 percent increase in the number of predoctoral research trainees being supported, over a period of five years.

To support the recommended number of trainees, the Committee suggests that the PHS research training budget be increased, as required, over the next few years.

In my professional opinion, the IOM/NAS report points clearly to the need to increase support for biomedical research training over the coming years. Special attention should be given to the following:

- multidisciplinary predoctoral research training programs;
- training targeted to the personnel needs of the American biotechnology industry;
- medical scientist (physician-researcher) training;

- training programs for minorities. This is based on the fact that a larger and larger proportion of the population is made up of minorities and that, by the year 2000, an estimated one-third of the new entrants to the workforce will be minorities.

Question. Given the shortages projected by both the National Science Foundation and the National Academy of Sciences, how many trainees do you think your Institute should be supporting, in your professional judgement?

Answer. In my professional judgment, the NIGMS should support 4,962 trainees in FY 1991, 956 more than could be supported under the President's budget request.

The Institute's Mission

Question. Dr. Kirschstein, your Institute conducts a lot of relatively basic research that supports the programs of all the other Institutes.

I wonder if you could give us a number of recent examples of how the work of your Institute supports, and has advanced, the research work of the other institutes.

Answer. The work of many NIGMS grantees has laid the foundation for countless research projects now funded by the other institutes at the National Institutes of Health. Presented below are some noteworthy recent examples:

- Cystic Fibrosis: In September 1989, after years of hard work, researchers finally accomplished the tour-de-force of identifying the gene responsible for cystic fibrosis (CF), a severe genetic disorder which occurs with significant frequency. Nearly all of the molecular and genetics techniques that made this accomplishment possible were developed over the past 20 years by NIGMS grantees. These include the use of restriction enzymes to cut segments of DNA, gene cloning, gene mapping by linkage analysis, and construction of somatic cell hybrids. Although the approximate chromosomal location of the CF gene was determined five years ago, its precise location and identification last fall depended on other techniques more recently developed by NIGMS grantees--chromosome walking and jumping and pulsed field gel electrophoresis. The demonstration that the suspected gene is really the one responsible for CF depended in part upon a computerized search of known DNA sequences in GenBank, the nucleic acid sequence database supported by a contract from NIGMS. This search showed that the protein encoded by the CF gene has a DNA sequence closely related to that of other genes which are known to encode proteins essential for the transport of substances across membranes. Both the National Institute of Diabetes and Digestive and Kidney Diseases and the National Heart, Lung, and Blood Institute support research on CF.

- Gene Therapy: A long-term goal of many clinicians is the treatment of hereditary disorders by gene therapy, the insertion of normal genes into diseased cells to compensate for a malfunctioning gene in the patient's own cells. NIGMS grantees have been studying homologous recombination in mammalian cells, a normally occurring process that results in the exchange of nearly identical genes between chromosomes. Dr. Oliver Smithies of the University of North Carolina and Dr. Mario Capecchi of the University of Utah are using homologous recombination to target foreign genes to specific regions of chromosomes. Because homologous recombination targets the foreign gene so specifically, this method avoids potential problems that could occur if foreign genes were inserted into inappropriate chromosomal locations. Gene targeting by homologous recombination is also being used to create animal models of human genetic diseases for which other suitable models do not already exist. For example, there is no appropriate animal model for cystic fibrosis (CF). Now that the human gene for CF has been identified, it might be possible to develop a group of mice with a similar defect, so as to test the effects of various therapies. Several Institutes, such as the National Institute of Diabetes and Digestive and Kidney Diseases and the National Institute of Neurological Disorders and Stroke, are supporting efforts directed toward gene therapy and the development of such animal models.

- Cancer-Causing Genes: Oncogenes are genes that, under certain circumstances, cause normal cells to undergo transformation into cancer cells. Scientists have generally accepted the hypothesis that oncogenes act by "turning on" genes that would ordinarily be "turned off," thus allowing cell growth to continue unchecked and resulting in the growth of a tumor. An NIGMS grantee, Dr. Ronald Evans of the Salk Institute, showed that the protein encoded by one oncogene, called c-erb, prevents gene transcription and the action of the normal "on" signal. Dr. Evans' finding was the first to demonstrate that preventing a gene from turning on can also cause a cell to become a cancer cell. This work, of interest to the National Cancer Institute, is forcing researchers to reformulate their thinking about how malignancies develop.

- Back Pain: For many years, an NIGMS grantee has been examining the mechanical properties of the spine with a view toward improving our understanding of this vital skeletal component from the point of view of an engineer--that is, exploring the structure and relative position of the parts of the spine and the forces interacting in it. During the course of this work, he and others developed a new method for studying the electrophysiological response of nerves which supply the facet joint of the spine. Since the facet joint has been implicated in the origin of lower back pain, this work is now being supported by the NINDS.

- Therapeutic Drug Design: The research area of structural biology has received considerable support from NIGMS in recent years. This work is aimed at determining the three-dimensional structure of biologically important proteins using, principally, the technique of x-ray crystallography. This research has advanced to the point where many investigators can now determine the precise structure of a biologically important enzyme. Then, they can actually design compounds to attach to the active site of the enzyme molecule, thus inhibiting its activity. Such "designed" compounds are often effective in fighting various diseases. One notable example of this application of structural biology to rational drug design is an NIAID-supported effort to develop a compound to counteract the cold virus. Another is work underway at several pharmaceutical companies to develop compounds active against the AIDS virus.

- Tumor Growth: NIGMS has long supported studies regarding the basic mechanisms underlying cell division and its control. Recently discoveries by some of the Institute's grantees have pointed to two proteins, maturation promoting factor (MPF) and cyclin, as being instrumental in controlling cell division. These proteins must be present in certain concentrations in order for the cell cycle to proceed, leading ultimately to cell division. With this important information in hand, cancer researchers are now investigating how the activation of oncogenes modulates the production of the two proteins, MPF and cyclin, necessary for cell division.

- Eye Disorders: A number of NIGMS grantees have been studying the ways in which cells synthesize and degrade a class of compounds known as cyclic nucleotides (CNs). These compounds are so-called "second messenger" molecules, critical to intracellular communication. Using a unique methodology to monitor how fast these CNs are metabolized, one NIGMS grantee discovered that CN metabolism was greatly speeded up when certain stimuli were applied, among them exposure to light. This work has evolved into an exploration, funded by the National Eye Institute (NEI), of the role of heightened CN metabolism in the process that occurs in the retina whereby a light stimulus triggers a nerve response leading to visual sensation.

- New Pharmaceuticals: Compounds that interact with DNA are of major importance for use as probes of gene structure and function, and as potential pharmaceuticals. One class of compounds of this type is the anti-sense oligonucleotides. These agents can bind either to genes themselves to prevent their expression, or to messenger RNAs to inhibit the translation of the genetic message into a protein. Grantees of the NCI and NIAID are using the findings from NIGMS-supported basic studies of these anti-sense oligonucleotides to explore their potential as anticancer and antiviral drugs. One NIGMS grantee has developed new methods to synthesize these oligonucleotides in sufficient quantity so that they can be readily used in the NCI and NIAID-funded research.

New National Center for Human Genome Research

Question. Dr. Kirschstein, this is the first year of the independent and separate Center for the Human Genome, which split off on October 1, from your Institute. I understand that approximately 9 employees transferred from your Institute to the National Center for Human Genome Research, and that you have continued to provide some overhead services to the new Center.

When will this arrangement be completed, or in other words, when will the Center be fully independent in terms of conducting all of its own necessary services?

Answer. Staff in the National Institute of General Medical Sciences continue to provide some overhead services to the National Center for Human Genome Research under arrangements we have worked out with the Center's leadership. Current plans are for this transition period to end by October 1, 1990, the beginning of FY 1991.

From Ideas to Application

Question. Traditionally, it has taken 10 to 15 years from the time a biomedical researcher has an idea or makes a new discovery and when that new discovery is actually put into common medical practice.

What is your experience? Has this traditional 10 to 15 year period been reduced in recent years?

Answer. When a scientist starts at the level of an idea for a research project in fundamental biology, it is impossible to predict where the research will lead, much less how long it will take to bear fruit. Indeed, the course of biomedical research is, almost by definition, a circuitous and lengthy process.

There is no doubt, however, that the availability of recombinant DNA techniques, new methods of catalysis, x-ray crystallography, and other sophisticated techniques, as well as the increasing use of computers, has accelerated the process of moving important research findings out of the laboratory into the clinical setting or toward commercialization. The development of new drugs, for example, has been revolutionized by the advent of "rational drug design," a new approach that is eliminating much of the trial and error in pharmaceutical development. I would also like to note a new laboratory technique, called PCR for polymerase chain reaction. Developed as recently as 1985, PCR is already in wide clinical use for the diagnosis of sickle cell anemia, Lyme disease, AIDS, and certain cancers.

Biotechnology Research Training Initiative

Question. For years, NIH officials have expressed concern about there not being enough research scientists entering careers related to biotechnology. A year ago, it was stated that a minimum of 250 trainees was needed now in various research training programs, with the goal of having 1,500 within a five year timeframe.

What has NIGMS done to come to grips with this situation? What incentives can you offer young scientists to compete for their services, and not lose so many to the private sector?

Answer. The NIGMS biotechnology research training program was established in FY 1989, in response to both the urging of the Senate Appropriations Committee and recommendations made by a panel of experts assembled at NIH in 1988. This panel recommended that the new program "ramp up" to a level of 1,500 trainees/year by the year 1993; and the Institute agrees that this is still a worthwhile long-term goal, given the continued rapid growth of the biotechnology industry. The Institute will support 190 biotechnology trainees in FY 1991, the same number being supported in FY 1990.

Minority Access to Research Careers Program

Question. Last year, the Committee recommended expanding the Minority Access to Research Careers Program to include eligible freshman year trainees. Were you able to accomplish this during the past year, and to what degree did this increase the funding level for the program?

Answer. As noted in a special report prepared at the request of the House Committee on Appropriations, the NIGMS has carefully studied the feasibility of extending the MARC Honors Undergraduate Research Training Program from the current support of students in the junior and senior years of college down to students in the freshman and sophmore years. Based in part on this study, the Institute currently plans to set up a pilot program to support freshman and sophomore students on a limited basis in FY 1991. Partly to accommodate this change, the FY 1991 budget request for the MARC Program includes a 25 percent increase over the FY 1990 estimate: $13.4 million in FY 1991 vs $10.7 million in FY 1990.

MBRS Program

Question. The Institute's other large minority research initiative, the Minority Biomedical Research Support Program, was to be transferred from the Division of Research Resources to NIGMS.

Was this carried out as planned? Are all minority research support programs now under the directorship of NIGMS?

Answer. The Minority Biomedical Research Support Program was transferred to the National Institute of General Medical Sciences effective October 1, 1989. The budget request for this program in FY 1991 is $32.3 million. Because the NIGMS also is responsible for administering the Minority Access to Research Careers Program, for which $13.4 million is proposed in FY 1991, the Institute will be directing the largest coordinated effort at NIH aimed at increasing the number of minorities pursuing biomedical research careers. However, the National Center for Research Resources will administer two programs, the Research Centers in Minority Institutions Program and the Minority High School Student Research Apprenticeship Program, both of which have complementary aims. In addition, all of the institutes, centers and divisions of the National Institutes of Health are now awarding special minority investigator supplements to ongoing research grants.

Nobel Prize in Chemistry

Question. Two NIGMS grantees were jointly awarded the Nobel Prize in Chemistry in 1989.

Would you briefly explain the nature of their research and why it is important, in layman's terms.

Answer. The co-winners of the 1989 Nobel Prize in Chemistry were Drs. Thomas Cech of the University of Colorado and Sidney Altman of Yale University. Both are grantees of the NIGMS' Genetics Program.

They received the award on the basis of their discovery, in 1982, that the genetic material, RNA, which was long believed to serve only as a message carrier in the genetic process, had important enzymatic properties. This is a very significant finding, because it is believed that such RNA enzymes, called "ribozymes," can be used to effectively attack and destroy certain infectious agents, such as the AIDS virus. According to the Swedish Academy, which awards the Nobel Prize, the discovery of Drs. Cech and Altman "...has altered the central dogma of the biosciences," and is likely to provide an important new tool in the control of viral infections.

Genetics Research

Question. The NIGMS administers the largest Genetics research program at NIH.

The Committee understands that there are over 4,000 genetic diseases, and that diseases with at least some genetic component are responsible for an estimated 15 to 20 percent of the Nation's annual health care bill.

Is there light at the end of the tunnel? Will the success of researchers in identifying the flawed genes responsible for cystic fibrosis and other disorders lead to new methods of diagnosis, treatment, and prevention?

Answer. I believe there is considerable light at the end of the tunnel. Over the past ten years, basic research in genetics, much of it supported by the NIGMS, has yielded important new tools and new information that are providing scientists with an understanding of the causes and consequences of many genetic diseases at the molecular level. This has already led, in many cases, to effective methods of detection, and, I believe it will eventually lead to effective methods of treatment and prevention as well.

The cystic fibrosis example is a good one. An estimated 12 million Americans carry the flawed gene responsible for this disease, the most common severe inherited disrder in the U.S. Since the gene responsible for cystic fibrosis was discovered in August of 1989, efforts have been underway, in laboratories all over the world, to use this new information to create efficient and accurate new methods of diagnosis. We are getting closer to that goal all the time.

Minority Programs

Question. The NIGMS has, for many years, been responsible for administering the Minority Access to Research Careers (MARC) Program. With the recent transfer of the Minority Biomedical Research Support (MBRS) Program to NIGMS, your Institute now has primary responsibility for minority targeted programs at NIH.

What do you feel needs to be done to attract more minorities into biomedical research careers? And, are you making any headway?

Answer. The alarm bell has been sounded by a number of high level panels regarding the immediate need to begin attracting greater numbers of minorities into biomedical research careers. Over the past two years, the National Academy of Sciences, the National Science Foundation, and the U.S. Task Force on Women, Minorities and the Handicapped in Science and Technology have all told us the same thing--that the pool of people from which future scientists must be drawn is shrinking, and that a larger and larger proportion of this pool is made up of minorities.

It is my belief that all of us, governments at all levels, state and local as well as Federal, must begin to devote more time and attention to science education. Teachers must make the learning of science more exciting. A recent Wall Street Journal article on the successful efforts of a science teacher at High Point School in Beltsville, Maryland shows, I believe, what can be accomplished by an energetic educator.

At the college and postgraduate levels, I believe the programs targeted to minority students supported by the NIGMS and other NIH components are helping. These programs have been given a high priority by the President in FY 1991, with a 25 percent increase for the MARC Program, $13.4 million, and an 8.4 percent increase for the MBRS Program, $32.3 million.

Opportunities in Biology

Question. The National Research Council of the National Academy of Sciences recently issued the results of a five year analysis, entitled Opportunities in Biology.

Doctor, could you briefly explain some of these opportunities for us, as they relate to the work of your Institute.

Answer. A tremendous amount of effort went into the creation of Opportunities in Biology, and I believe it represents an excellent analysis of the biomedical research opportunities that currently exist, awaiting exploitation. As noted by the authors, who include many of the Nation's top researchers, we are now on the threshold of a number of major advances in the biological sciences, because of the availablity of new techniques, powerful computers, and imaginatively constructed instruments.

Some of the opportunities which relate specifically to NIGMS-supported programs include the following:

- Structural Biology--Proteins, carbohydrates, nucleic acids, and other biological molecules all play very specific roles in sustaining life. And, they must act in very precise ways in order to avoid cellular dysfunction. They can only do this, however, if they possess just the right three-dimensional shapes. It therefore follows that an understanding of how a disease occurs can be obtained through a knowledge of how a given molecule must be shaped to work properly, as well as the consequences of structural flaws. It also follows that, in situations where a disease is known to be caused by a misshapen protein, one with the proper shape might be artificially produced and used to correct the defect, thus treating the disease. However, this has proven to be an extremely complex undertaking, in that researchers have had serious difficulty getting manufactured proteins to "fold" properly. Advances in technology have made this a very "hot" research area, and one considered ripe for major advances. Support for research on structural biology is an emphasis area of the Institute's Biophysics and Physiological Sciences Program.

- Cellular Signaling--As noted by the authors of the report, "An area of cell research of special relevance to medicine is that centering on cell to cell communication. Growth factors, hormones, and their receptors...create a communication network that allows the cell to react to its surrounding environment. Many disease conditions, including cancer and certain types of mental illness, are believed to result directly from abnormal cellular regulation" caused by failed signaling. The combined application of many molecular techniques, report the authors, "is leading to rapid and impressive advances" in this area, which is currently a field of high priority within the NIGMS' Cellular and Molecular Basis of Disease and Pharmacological Sciences Programs.

- Genetics--The authors note that "the combination of classical genetics and biochemistry has resulted in an explosion of genetic understanding" that has opened up research opportunities on a vast scale in all areas of genetics. Some of these areas are: genetic analysis; gene expression; DNA replication, gene recombination; DNA repair and mutagenesis; and genome organization. These are all areas receiving support from the Institute's Genetics Program.

Question. To what extent will your 1991 budget request allow you to take advantage of these opportunities?

Answer. The NIGMS budget request for FY 1991 will allow us to fund four more research project grant awards, 3,200, than we did in FY 1990. While this is not an optimal level, it will allow us to adequately support the most exciting research opportunities.

G-Proteins

Question. In your justification material, you note that one of your grantees, Dr. Alfred Gilman of the University of Texas Southwestern Medical Center, received the prestigious 1989 Lasker Award for Basic Biomedical Research.

Dr. Gilman's work was concerned with G-proteins. Could you briefly explain the importance of his research.

Answer. Working with support from the NIGMS' Pharmacological Sciences Program, Dr. Gilman discovered G-proteins about 10 years ago. These are a family of membrane-bound proteins that are now recognized to play a vital role in communication between cells.

As noted in the National Research Council's report Opportunities in Biology, "Growing knowledge of G-proteins has already contributed significantly to a molecular understanding of human disease." This includes an increased understanding of the pathogenic toxins responsible for both cholera and whooping cough. An understanding of how G-proteins act has also led to research on their likely role in a number of genetic disorders. One such disorder, referred to as PHP-1, has already been identified. PHP-1 causes hyperglycemia, mental retardation, and convulsions.

Chemzymes

Question. Dr. Kirschstein, in your opening statement, you refer to the work of one of your grantees, Dr. Elias Corey at Harvard, who recently developed something called "chemzymes."

Last July, an article published in the journal Science indicated that experts at both universities and American pharmaceutical firms regarded Dr. Corey's work as "enormously helpful to synthetic chemists, the people who make things, and one of the most exciting things in academic research."

Could you please elaborate on Dr. Corey's work for us?

Answer. There is no doubt that the work coming out of Dr. Corey's laboratory is very exciting indeed, and will be of great benefit to America's pharmaceutical and chemical manufacturing industries.

The so-called "chemzymes" developed by Dr. Corey are artificial enzymes or catalysts that allow chemists much greater control over the chemical reactions they must use to produce substances of medicinal and commercial value. Indeed, one of the most important characteristics of chemzymes is that they permit scientists to produce only the form of a chemical or drug which is most efficient in its action --an ability that both saves time and money and eliminates undesireable side effects.

One illustration of the practical effects of Dr. Corey's work is noted in a recent issue of Science News, which reports that, "Dr. Corey's group has designed a chemzyme that catalyzes the first of a series of reactions for making prostaglandins, a family of naturally occuring chemicals that regulate blood flow, blood pressure, and other vital signs. Physicians use prostaglandins to induce labor and treat ulcers, among other things... With the new approach,...the whole synthesis process is easier and more cost effective."

Medical Scientist Training Program

Question. The NIGMS supports a unique research training program, which provides support to individuals seeking the combined M.D./Ph.D. degree.

Doctor, what is the purpose of this program?

Answer. It is vitally important for the Nation to maintain an adequate pool of physician-scientists, people trained in medicine and in using research laboratory techniques to creatively solve biological problems. But, because of a variety of factors, including the huge debt that most young physicians now carry away with them from medical school, a smaller and smaller proportion of new physicians are entering careers in research. As a symptom of this problem, the number of M.D.s who are principal investigators on NIH grants has dropped 10 percent since 1970.

The Medical Scientist Training Program (MSTP) addresses this problem by providing support for topflight students who wish to obtain the combined M.D./Ph.D. degree. Experience shows that over 80 percent of combined degree graduates enter and stay in research careers, and they tend to outperform other groups, in terms of having success in obtaining research grants, as well as in other measures of research productivity.

Question. How many trainees will you be able to support under this program in 1991?

Answer. The Institute's FY 1991 budget request provides $17 million for the support of an estimated 735 MSTP trainees. This is the same number supported in both FY 1989 and FY 1990.

Question. Is this the optimal number?

Answer. The recent Institute of Medicine/National Academy of Sciences report on personnel needs in the biomedical sciences suggests that the need for physician-researchers will increase over the coming years. And, most experts agree with this assessment. In my professional judgment, I believe the optimal number of MSTP trainees, in FY 1991, would be about 800.

Research Project Grants

Question. Dr. Kirschstein, your 1991 budget request provides for 3200 research project grants. How does this compare with the number of grants supported in recent years?

Answer. The NIGMS supported 3,261 research project grants in FY 1989, and will support about 3,196 such grants in FY 1990. Support has, therefore, been fairly level over the past few years.

Question. What percentage of your approved applications for new and competing renewal awards will you be able to fund? And, how does this compare with recent years?

Answer. The NIGMS will be able to fund an estimated 26 percent of approved research grant applications in FY 1991. This compares to 23 percent in FY 1990; 29 percent in FY 1989; and 40 percent in FY 1988.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

Efforts to Attract Minorities into Research Careers

Question. Dr. Kirschstein, in light of the historically low participation of minorities in the field of bio-medical research and future projections that, by the year 2000, one-third of the persons entering the American work-force will be minorities, what steps has the Institute taken to attract minorities to the field of biomedical research?

Answer. The National Institute of General Medical Sciences administers two programs that are specifically designed to attract minority students into biomedical research careers. The first of these, the Minority Access to Research Careers (MARC) Program, provides support for research training activities to schools with high levels of minority enrollment, under the authority of the National Research Service Act (NRSA). Roughly 80 percent of the MARC Program budget is allocated to an Honors Undergraduate Research Training program, which has the goal of increasing the number of minority college students gaining admittance to outstanding Ph.D. programs in the biomedical sciences.

The second program, newly transferred to the Institute in October 1989, is the Minority Biomedical Research Support (MBRS) Program. This program provides support for student and faculty research activities at colleges and universities that enroll large numbers of underrepresented minorities in science programs.

Question. How many minority trainees do you anticipate supporting in FY '91? How does this compare to FY '89 and FY '90?

Answer. The President's budget request for FY 1991 provides approximately $13.4 million for the MARC Program, a 25 percent increase over FY 1990. This will allow the support of 711 MARC trainees in FY 1991, compared to 575 trainees in FY 1990, and 479 trainees in FY 1989.

The MBRS Program's budget for FY 1991 is $32.3 million, an 8.4 percent increase over FY 1990. Beyond this, however, as in past years, roughly $11 million in cofunding support is expected from other NIH and Departmental components. These funds will support research positions for an estimated 1,101 undergraduate and 448 graduate students, as well as research projects for about 750 faculty members.

These are the same numbers of research positions and research projects supported in both FY 1989 and FY 1990. The increased funding provided in FY 1991 will be used to pay the costs of increased student salary levels.

Question. Is the Institute able to report to the Committee progress in attracting young minority investigators?

Answer. The MARC and MBRS programs have established excellent records of success, both in attracting minority students into biomedical research career tracks and in developing the research capabilities of minority institutions. A 1984 survey found that 76 percent of former MARC Honors Undergraduate students enrolled in graduate or pro-fessional school programs after college. Similarly, a 1987 analysis found that 254 former MBRS students had earned the Ph.D. degree (163 in the life sciences, 65 in engineering or mathematics, and 26 in other areas).

The success of these two programs was highlighted in a 1988 report issued by the U.S. Task Force on Women, Minorities, and the Handicapped in Science and Technology, which stated the following.

> "Of Federal programs established to give minorities and women access to science and engineering, we found the Minority Access to Research Careers (MARC) of the National Institutes of Health closest to what we need today. MARC is a prime example of a successful Federal intervention program...The NIH's Minority Biomedical Research Support (MBRS) program is also effective in enhancing the research careers of faculty."

Despite the success of these two programs, it is still true that less than 2 percent of the Ph.D.s in the biological sciences are being earned by minorities.

Predoctoral Research Training

Question. Dr. Kirschstein, I understand the National Academy of Sciences recently released a report which concluded that funding for 4,300 trainees in basic molecular science per year was necessary to ensure an adequately trained pool of biomedical researchers in the future.

Do you agree with the recommendation of the Academy?

Answer. The report to which you refer was just released by the Committee on Biomedical and Behavioral Research Personnel, a component of the Academy's Institute of Medicine.

Based on demographic data that indicate "a projected undersupply of biomedical Ph.D. scientists into the next century," the Committee recommended that the Public Health Service (PHS) provide support for 4,300 predoctoral trainees (as measured in terms of Full Time Equivalents or FTEs) in the biomedical sciences by 1990. The Committee went on to recommend a gradual increase in support for predoctoral trainees to a level of 5,200 FTE trainees by the year 1993.

I have read the Academy report and found it convincing. Therefore, I agree with the recommendation that support for predoctoral training should be increased, if funds become available.

Question. How does the FY '91 budget compare to the 4,300 trainees recommended by the report?

Answer. The Academy recommended that the PHS support 4,300 predoctoral FTE trainees in FY 1990 and 4,600 FTE trainees in FY 1991. For NIGMS, which has traditionally funded about 60 percent of the PHS total of predoctoral trainees, the Academy's recommendations translate into approximately 2,967 students (2,580 FTEs) in FY 1990, and 3,174 students (2,760 FTEs) in FY 1991.

By comparison, the Institute's FY 1991 budget request provides for 2,065 predoctoral students (1,795 FTEs) in the biomedical science categories referred to by the Academy. This is 902 students (784 FTEs) short of the Academy's recommendation for FY 1990, and 1,109 students (964 FTEs) short of the Academy's recommendation for FY 1991.

Question. How much would it cost to implement the recommendation in FY '91?

Answer. The average cost of training a predoctoral student is $19,200/year. For NIGMS programs, it would therefore cost an additional $17.3 million over the amount provided in the President's FY 1991 budget request to support the number of trainees recommended by the Academy for FY 1990, and an additional $21.3 million to reach the Academy's recommended level for FY 1991.

NATIONAL EYE INSTITUTE

STATEMENT OF DR. CARL KUPFER, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. We next go to the National Eye Institute, Dr. Kupfer. We welcome you this afternoon. Your Institute stands out as having the highest award rate for research project grants.

The overall NIH average for 1989 was 29.4 percent, as we discussed earlier in the day, and your Institute was able to fund 46.8 percent of the approved applications.

Your request next year is for $247.39 million, for a 4.59 increase. Welcome and please proceed.

Dr. KUPFER. Thank you, sir. I would like to make some brief comments about the activities in vision research during the last year. We continued to provide new information that increases knowledge in several very broad fields: in the cause of cancer; in regeneration in the central nervous system, and this is particularly appropriate inasmuch as we are entering the "Decade of the Brain"; and in reducing the complications of diabetes.

With respect to the cause of cancer, investigators supported by the National Eye Institute have recently identified and isolated the gene that causes a type of eye tumor called retinoblastoma, and the exciting thing about this gene is that the tumor will only develop if the gene is absent from the tissue.

It has now been found that this gene, the retinoblastoma gene or RB gene, actually produces a protein that suppresses tumor growth. There have been recent experiments to demonstrate that one can introduce this RB gene back into tumor cells and convert them into normally growing cells.

Finally, it has also been found that this retinoblastoma gene does play a role in other cancers, including breast carcinoma, small cell lung carcinoma, and osteosarcoma of the bone. This has some very important implications. So, we are going to see some very major changes in the approach to cancer biology as a result of these studies.

The second area has to do with transplantation of tissue in the brain or central nervous system. The tissue I am referring to is the retina of the eye, which is in fact part of the central nervous system.

It has now been shown that one can use a strain of rats that ordinarily undergo a degeneration of the retina and by introducing normal cells from another strain of rats, prevent the retinal degeneration. In fact, there can actually be regeneration of the cells that hitherto have been destroyed.

This is a major step forward in the whole area not only of regeneration in the central nervous system, but also of the maintenance of the regenerative capacity of adult tissue after the embryonic tissue matures.

You mentioned spinal cord research earlier and a recent advance in this area illustrates how sometimes investigators who are interested in one topic will unexpectedly make very important finding which impacts on another area. In this regard, most recently, it has been shown by NEI supported investigators that if one takes some embryonic connective tissue and puts it on a milipore filter, then crushes the spinal nerve of an experimental animal, and then places this filter with the embryonic connective tissue at the site of the crush, one can actually see regeneration of the nerve fibers crossing that crushed area of spinal cord. This indicates that it is possible to maintain regenerative capacity in the adult central nervous system under some very special conditions. These findings are being applied to the optic nerve which is similar to the spinal cord, because it is also part of the central nervous system.

Finally, as far as the complications of diabetes are concerned, we have recently completed the early treatment diabetic retinopathy clinical trial. There were three major findings. The first relates to a major cause of blindness in diabetes that is due to edema or accumulation of fluid in the macula in the region of the retina that has the highest capability of vision. The study showed that one can reduce blindness from edema by 50 percent using laser treatment.

The second finding which is very important, is that it is not necessary to treat the early phase of diabetic retinopathy until certain observable high-risk characteristics develop. This is not only of great benefit to the patient in the sense that he or she would not have to undergo treatment until it is absolutely essential, but, as one might imagine, the economic impact of this information is also very important.

Finally, there was a hypothesis that aspirin might slow down the development of diabetic retinopathy. We found that this is not the case, but what was equally important was that diabetics can take aspirin and not increase their chances of hemorrhage.

PREPARED STATEMENT

I would also like to briefly mention that the National Eye Health Education Program is proceeding. As part of it, we are engaged in disseminating the results of this recent diabetic retinopathy clinical trial to patients and eye care practitioners. We are also involved in getting other information about diabetic retinopathy and glaucoma out to the populations at highest risk for these diseases.

The budget request for fiscal year 1991 is $247,392,000. I would be pleased to answer questions.

[The statement follows:]

STATEMENT OF DR. CARL KUPFER

Mr. Chairman and Members of the Committee, it is always gratifying for me to be able to tell you about progress in vision research supported by the National Eye Institute (NEI). Over the years this progress has been significant even though confirmation of new research findings is sometimes a long and arduous task. This year, however, I am especially happy to tell you about several research findings that either strengthen or confirm earlier scientific hypotheses reported in this same forum in the past two or three years.

Three years ago, I told you about NEI-funded researchers who identified, cloned, and characterized the defective or missing gene that leads to retinoblastoma (RB). RB is a cancer of the eye that occurs in children who often later develop other cancers. RB can mean loss of the eye or even death. This was the first time that the cause of a cancer was found to be a partial or complete loss of a gene that normally produces a protein to suppress tumor growth. Using this finding, the researchers then developed a blood test that can be used to determine whether a child in a family with a history of RB has inherited the RB gene from a parent.

More recently, other NEI-funded scientists inserted clones of a healthy RB gene into RB tumors grown in laboratory cultures. The tumors stopped growing and the cells began to differentiate into normal tissue. This work confirms the suppressor gene hypothesis and suggests that gene therapy for RB may be possible.

Although this molecular genetics research has pinpointed the cause of the cancer, a major obstacle in RB research has been the lack of an animal model to study the dynamics of how benign cells in the eye become malignant. Now, however, NEI grantees have developed a line of mice with inherited eye cancers that are the same as human RB in cell type, structure, biochemistry, and in the way the malignancy develops. With the mouse model, we can study the process of malignant transformation from inception through proliferation and metastases. The model should also be valuable for developing and testing drugs to counteract the lack of the control protein.

In another area of basic research, scientists are making rapid progress in replacing deteriorated cells of the retina with healthy cells. Last year I reported that researchers had taken strips of pigment epithelial (PE) cells from newborn rats and transplanted them into damaged retinas of adult rats with a genetic mutation that progressively destroys the light-sensitive photoreceptors. PE cells ensure the proper functioning of photoreceptor cells by supplying nutrients and removing waste products from them. The transplanted PE cells stopped the degeneration and rescued populations of nerve cells that otherwise would have died from the inherited disease. Other NEI-funded researchers have now transplanted the photoreceptor cells themselves, which survive transplantation and appear to be metabolically active for at least six weeks.

In immune studies that complement this transplantation work, NEI intramural researchers are developing molecular probes to isolate the specific protein on white blood cells that is likely to cause graft rejection. If the protein is identified, the investigators will begin to devise ways to neutralize its immune action. This type of concerted, creative research offers hope that one day we may be able to rescue or replace degenerating retinal cells in diseases such as macular degeneration and retinitis pigmentosa.

Retinitis pigmentosa (RP) is a group of inherited retinal degenerative diseases that affect otherwise healthy teens and young adults. RP types differ in several ways--inheritance pattern, time of onset, severity, and progression--but all have the same end-state of blindness. In addition to the cell transplantation work, vision researchers are making progress on two other fronts--identification of a biochemical error outside of the eye in one type of RP and a specific genetic defect in another type.

National Eye Institute intramural biochemists have been studying a breed of highly inbred poodles that naturally develop a retinal degeneration similar to human RP. This disease is caused by a recessive gene found in the non-sex cells of both parents. The researchers found that, in both healthy and affected dogs, the rod photoreceptors cells produce only very small amounts of DHA, a fatty acid that is needed in high levels to maintain the health of the highly active rods. This suggested that some other organ, probably the liver, produces the required high levels of DHA, which is then delivered to the eye. When the dogs' blood was tested for the presence of DHA, they found that the affected dogs, but not the healthy dogs, had very low levels of circulating DHA. Other researchers had found that blood levels of DHA are also low in RP patients who have the recessive type of RP, thereby supporting the theory of a biochemical error in an organ other than the eye. The next logical step is to determine whether a dietary supplement of DHA can slow or halt disease progression in the dogs.

Molecular genetics research on RP is also making great headway. Within a year after one NEI-supported scientist had mapped the gene for the dominant form of RP to an area of chromosome 3, another group of NEI grantees identified and characterized the specific gene that produces a protein called rhodopsin. Rhodopsin is the protein that enables photoreceptors to respond to light. From earlier NEI-funded research, the scientists already had blood samples from about 1600 RP patients to begin immediate study of genetic patterns in the mapped chromosomal area. In 17 of 148 of their samples from unrelated dominant-type RP patients, they found a transposition of just two DNA elements on the gene that normally produces rhodopsin. Because of this transposition, the scientists believe that the aberrant gene codes for a disfunctional rhodopsin. None of the unaffected controls and only a small subset of the dominant RP patients had this transposition, further showing how varied are the retinal degenerations we cluster under the term RP. I think that these research advances nicely illustrate the importance of interaction among various scientific disciplines.

During this past year, we have also gotten results from clinical studies of treatments for glaucoma and diabetic retinopathy. The Fluorouracil Filtering Surgery Study is a multicenter, randomized study investigating whether postsurgical injections of the drug 5-fluorouracil, or 5-FU, would increase the success rate of glaucoma filtering surgery. Creation of a surgical drainage channel, or filter, is standard treatment for patients whose elevated intraocular pressure can no longer be controlled with drugs. 5-FU was used in the expectation that it would impede the growth of scar tissue that sometimes blocks the surgically created channel, thereby necessitating another filtering operation that has even less chance of success.

Early study results show that one year after surgery, only 27 percent of the patients who received 5-FU needed reoperation, compared to 50 percent of those who had surgery alone. Moreover, in the surgery alone group, only about one-third could maintain satisfactory intraocular pressure without medications, compared to two-thirds of those receiving 5-FU. Furthermore, of the patients needing medication, those in the 5-FU group needed lower doses and fewer types of medication than did those who had surgery alone. The next steps are to study the long-term safety and efficacy of the drug.

To improve the outcome of treatment for diabetic retinopathy, which treatens the sight of the 11 to 12 million Americans with diabetes, the NEI initiated the Early Treatment Diabetic Retinopathy Study (ETDRS) in 1979. The ETDRS was designed to investigate three questions: Is laser treatment effective for diabetic macular edema, which is a swelling of a part of the retina that provides sharp, straight-ahead vision? When in the course of the disease progress is the best time to begin laser treatment for diabetic retinopathy? Does aspirin treatment alter the progression of diabetic retinopathy? The controlled, multicenter clinical trial, begun in 1979, enrolled 3,711 patients at 22 centers.

Final results support earlier study findings that laser treatment of macular edema reduces by half a patient's risk of visual loss. The study also showed that, if a patient with early diabetic retinopathy is followed regularly, laser treatment may be safely deferred until the disease progresses to a more advanced stage, thereby sparing the patient from the possible siade effects of treatment until sight is threatened. It also showed that although 650 mg of aspirin taken daily did not prevent or slow the progression of retinopathy, neither did it increase the risk of progression. This latter finding may be important to diabetic patients who have twice-the-normal risk for developing cardiovascular disease, which might require daily aspirin therapy.

In closing, I would like to describe work in two areas of research that are important for future vision research. We know that certain eye diseases are related to the aging process, but we lack accurate and current information about the prevalence of blindness and visual impairment among older people. The Baltimore Eye Survey was funded to provide this information by studying a large, multiracial population that could serve as a model for many urban areas in the United States.

The survey determined the prevalence of blindness and visual impairment among blacks and whites 40 years and older who come from comparable socioeconomic settings. A population-based sample of 5300 blacks and whites received an ophthalmologic screening examination that included detailed visual acuity measurements. From this sample, the researchers estimate that more than 3 million Americans 40 years or older are visually impaired and 890,000 of these are bilaterally blind.

The survey found that prevalence of blindness and visual impairment in blacks was double that of whites. The rates of vision loss for both groups rose dramatically with age, but there was no difference between males and females in the rise. The researchers also found that more than 50 percent of the subjects had improved vision after refractive correction, some improving by three or more lines on the eye chart.

In the older segment of the population, the need for cataract surgery will constantly expand as more and more people enter their 70s and 80s. Currently, cataracts cause visual disability for about 20 percent of Americans in their 70s and for about 50 percent for those in their 80s. Americans annually spend about $3.5 billion to have cataracts removed. We calculate that if some way could be found to delay the need for surgery by just 10 years, the annual number of cataract operations could be cut in half at a significant annual savings to the Nation. Cataract prevention, therefore, is an important NEI research goal.

Currently, several drugs are showing promise for slowing or halting the development of cataract, but, until recently, we have lacked a reliable method for classifying subtle differences in lens opacities. Such a method would be essential for monitoring the effectiveness of a candidate drug. Now NEI scientists have developed a Lens Opacities Classification System that makes it possible to grade/classify cataracts accurately and pinpoint fairly subtle lens changes.

Because the new system is easy to use and users reach almost perfect agreement on cataract classification, it should also be valuable for field studies of cataracts in various parts of the world. Investigation of questions about whether altitude or sunlight affect cataract development may provide important clues about mechanisms involved in cataract development and may lead to methods of prevention. These are but a few examples of how our investment in vision research is producing significant returns in clarifying the underlying process of several blinding eye disease and in advancing our ability to prevent blindness.

Mr. Chairman, the FY 1991 budget request for the National Eye Institute is $247,392,000. I will be happy to answer any questions.

BIOGRAPHY OF DR. CARL KUPFER

February 9, 1928. New York, New York.

Education: A.B., Yale Univ., 1945-48. M.D., The Johns Hopkins Medical School, 1952 Certified. Amer. Bd. of Ophthalmology, 1958.

Professional History: Internship and Assistant Residency, Wilmer Eye Inst., Johns Hopkins Hospital, 1952-54. Lab. Assistant, Biostatistics, Johns Hopkins School of Medicine, 1953-58. Research Fellow in Ophthalmology, Harvard Medical School, 1958-60. Instructor in Ophthalmology, Harvard Medical School, 1960-62. Asst. Prof. of Ophthalmology, Harvard Medical School, 1962-66. Prof. and Chairman in Ophthalmology, Univ. of Wash. School of Medicine; Research Affiliate, Univ. of Wash. Primate Ctr., 1966-70.

Professional Organizations: Amer. Physiological Society; Assoc. for Research in Vision and Ophthalmology; American Academy of Ophthalmology; American Ophthalmological Society; Pan American Ophthalmological Society; Johns Hopkins Univ. Soc. of Scholars; Member, Inst. of Medicine, National Academy of Sciences.

Honors and Awards: The Secretary's Special Citation, Dept. of Health, Education and Welfare (DHEW), 1972; The Superior Service Award, DHEW, 1974; Presidential Rank Award of Meritorious Executives, 1983; Migel Medal, Amer. Foundation for the Blind, 1976; Public Service Award in Ophthalmology, Amer. Acad. of Ophthalmology and Otolaryngology, 1977; Special Award of Honor, The Assoc. for Research in Vision and Ophthalmology, 1983; David Rumbough Memorial Scientific Award, The Juvenile Diabetes Found., 1983; The Lighthouse Pisart Vision Award, 1984; Cavera Medal of Univ. of Rome, 1985; The Mildred Weisenfeld Award for Excellence in Ophthalmology, 1987. Dunphy Lecture, 1977; Lorand V. Johnson Lecture, 1980; C. Dwight Townes Memorial Lecture, 1981; Glenn A. Fry Award Lecture, Amer. Acad. of Optometry, 1981; Richard Stein Lecture, Maurice and Gabriella Goldschleger Eye Inst., Tel-Aviv Univ., Sackler School of Med., Israel, 1982; Jules Stein Lecture, L. A., Calif., 1983; Bowman Lecture, The Ophthalmological Soc. of the U. K., London, England, 1984; Seymour Roberts Memorial Lecture, Stanford Univ. Med. Ctr., Stanford, Calif., 1984; Doheny Lecturer, Univ. of So. Calif., 1984; Everett Kinsey Lecturer, Contact Lens Assoc. of Ophthalmologists and International Soc. for Refractive Keratoplasty, Las Vegas, Nevada, 1987. Editorial Bd, Investigative Ophthalmology, 1969-1977; Editorial Bd, American Journal of Ophthalmology, 1971-1983; Mbr, Scientific Advisory Committee, Fight for Sight, 1971- present; Mbr, National Diabetes Advisory Board, 1976-present. Mbr, Board of Trustees, Helen Keller International Inc., 1975-present; Coord. U.S.-Japan Collaborative Agreement in Vision Research, 1976-present; Mbr, International Vitamin A Consultative Group, WHO, 1973-present; Mbr of U.S. Delegation to World Health Assembly, 1978; Mbr, WHO Advisory Group for Prevention of Blindness Prog., 1978-1984; Consultant, Pan American Health Org., 1978-present; Coord. for USA, Priority Area "Eye Diseases," U.S.-U.S.S.R. Prog. for Health Cooperation, 1978-present; Mbr, WHO Expert Advisory Panel on Trachoma and Prevention of Blindness, 1979-present; Dir., WHO Collaborating Ctr. for the Prevention of Blindness, National Eye Inst., Bethesda, MD, 1979-present; Pres., International Agency for the Prevention of Blindness, October 1982-present.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. Thank you very much, Dr. Kupfer. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

NATIONAL EYE HEALTH EDUCATION PROGRAM

Question. In the fiscal year 1990 report, the Committee urged your Institute to push for full implementation for a National Eye Health Education program. For example, I understand that 50 percent of diabetic patients are not receiving available treatment in order to maintain good vision. Glaucoma is another chronic situation which can be effectively managed if people are aware of the need to seek help. What is the status of this Health Education program?

Answer. This past year has been a busy and productive one for the National Eye Health Education Program (NEHEP). Some of the activities recently undertaken include the following:

One of the NEHEP's four operating principles is to extend the reach and effectiveness of the program through the use of intermediaries--professional, voluntary, and civic organizations; other government agencies; and private industry groups with an interest in eye health. This approach maximizes the amount of resources available for the program because the private sector can provide support for the development of materials and delivery of educational messages to NEHEP target audiences.

To help build NEHEP's intermediary relationships, the NEI hosted a national Planning Conference last March, with more than 65 participants representing a diverse group of 35 professional, voluntary, and government organizations as well as pharmaceutical companies. Conference participants offered many recommendations for NEHEP activities, on which NEI staff have been working.

To guide the program, recommendations have been developed for the establishment of a formal, two tiered, advisory structure consisting of a small Planning Committee and a larger group called the NEHEP Partnership. The Planning Committee includes members with expertise in key NEHEP program areas who will provide advice on the development, implementation, and evaluation of NEHEP activities. The first Committee meeting was held in January 1990, at which NEI staff presented recommendations for NEHEP projects currently in development and those planned for the future. The group endorsed all of these recommendations, including plans to conduct a national survey of public knowledge, attitudes, and practices about eye health; development of a pilot test for a national toll-free telephone information service to answer the public's questions on eye health; and selection of the first two target audiences at which to direct NEHEP activities. The audiences are: people with diabetes to receive messages about early detection and timely treatment of diabetic retinopathy, and blacks over age 50 who are at high risk for glaucoma to receive messages about early detection and appropriate treatment of this disease.

The second tier of the advisory structure, the NEHEP Partnership, will consist of representatives from professional associations, voluntary and civic organizations, and other groups concerned with eye health and which represent important NEHEP target audiences. These organizations will be invited to join the program soon. With the help of the Planning Committee and the Partnership organizations, the NEI is developing strategic plans to reach the first two designated target audiences with eye health education messages and materials.

A major objective of the NEHEP is to serve as a national resource for information about eye health education programs and materials. By serving as such a resource, the Program can avoid costly duplication of effort and can contribute to the exchange of ideas and information. To this end, an eye health education subfile has been established for the Combined Health Information Database, which represents a cooperative effort of many Federal government agencies. The eye health subfile became accessible in January 1990, and new information will be added on a quarterly basis.

Because it is critical to evaluate whether the expenditure of Federal funds for the NEHEP has an impact on the public's health, we are building a research and evaluation component into the Program. As the first step, a research project has been planned that will provide baseline data on the knowledge, attitudes, and practices of NEHEP target audiences regarding health care and eye disease.

As part of this research effort, a series of focus group discussions will be conducted with small groups representing the two initial target audiences: blacks over age 50 who are at risk for glaucoma and people with diabetes and their families. The focus groups will help obtain insight into what these populations know about the risk of blindness from glaucoma and diabetic retinopathy and how the NEHEP can best deliver messages to encourage appropriate eye care. The focus group discussions will also provide information important to the development of the national survey.

While these projects have received the greatest emphasis during the past year, other information activities relevant to the NEHEP have also been undertaken. Two important projects involved disseminating recently announced results of two NEI-supported clinical trials, one that studied treatment for diabetic retinopathy, the Early Treatment Diabetic Retinopathy Study (ETDRS), and one on glaucoma treatment, the Fluorouracil Filtering Surgery Study. For each trial, NEI staff prepared a variety of information materials for both national distribution and dissemination from participating clinical centers. Staff also made presentations at meetings of the of investigators for each trial about how to conduct publicity activities in their cities that would mesh with national media activities.

For the ETDRS study, an exhibit was developed and staffed at the annual meetings of the American Academy of Ophthalmology and the American Academy of Optometry and a fact sheet for patients was written and distributed that explained the study's conclusions. To make certain that all ophthalmologists treating diabetic patients knew of the ETDRS conclusions, a clinical alert letter was prepared and, with the assistance of the American Academy of Ophthalmology, mailed to 22,000 ophthalmologists around the world. NEI staff also recently participated, at the invitation of the National Society to Prevent Blindness, in activities proclaiming the week of November

12, 1989 as Glaucoma Awareness Week. This involved preparation of a proclamation for President Bush's signature, and participation in national press activities.

With all of these projects, the NEI has embarked on some very exciting activities related to the NEHEP. We look forward to a busy and productive year as we continue work on these initiatives and to new opportunities that may arise.

AWARD RATE

Question. Dr. Kupfer, we hear again and again concern expressed about the low and declining percentage of approved grants that are actually funded. The average for NIH for this current fiscal year is estimated to be 24 percent which drops all the way to 18 percent for several of the institutes. Your Institute, however, has a funding rate of approved grants of over 40 percent. What is it that permits you to fund such a high percentage of approved grants?

Answer. The budget increase for the NEI in FY 1990 is only about 2.4%, the second lowest of any research institute as compared to approximately 5.8% for NIH as a whole. The higher award rate for research project grants is a direct result of the Institute's deliberate and long-standing policy of making individual, investigator-initiated research project grants its principal support mechanism. And, within the research project grants category of awards, the NEI supports a very different mix of award mechanisms from many of the other NIH funding components. For example, the NEI does not support any program projects or any other type of large, umbrella-type awards such as multi-project center awards. One must take care, then, in trying to compare the NEI's relatively high award rate, based largely on traditional research projects (R01) and first independent research support and transition awards (R29) awards, with that of other NIH components which are using these large umbrella-type mechanisms to a significant extent. It is really an "apples and oranges" comparison. Further, the NEI funds very few research and development contracts. An NEI staff analysis (Figure 1) has demonstrated that if the NEI were to use these various mechanisms in the same proportion as the other institutes, its award rate would be nearly identical to the NIH average. In short, by funding mostly R01 and R29 grants, the NEI is able to keep its average grant costs low (they are the lowest at NIH) and, therefore, the NEI is able to fund additional grants.

LACK OF RESEARCH CENTERS

Question. Why does the Eye Institute, unlike the other Institutes, not have research centers?

Answer. The NEI does not at present support any specialized or comprehensive centers. The National Advisory Eye Council and the community of vision researchers have strongly supported NEI's long-standing policy that priority should be given to individual research project grants, each competing on its own merits. Even in the arena of fixed-protocol clinical studies, e.g., clinical trials and other epidemiological studies, NEI has insisted that each individual study undergo peer review before its initiation.

Question. Do you find you are able to accomplish all that is necessary without the use of research centers?

Answer. It is also possible, of course, that in the future some vision research opportunities might require the use of a specialized center mechanism of support. At the present time, however, we have been able to accomplish what is necessary using individual research support grants and cooperative agreements. We do have centers if you consider a grouping of various types of support to a well coordinated eye research department as a research center. For example, it should be pointed out that a number of coordinated, focused vision research groups do exist around the country. The investigators in those "centers" receive the major source of their outside funding from NEI R01 grants. The Eye Research Institute in Boston, the Jules Stein Eye Research Institute in Los Angeles, and The Cullen Eye Institute in Houston are three prominent examples.

COMPOSITION OF RESEARCH GRANTS STUDY

Question. Dr. Kupfer, I understand that your Institute is doing a study of the composition of grants that will address all of the issues that relate to the continuing escalation and the growth in size of grant applications.
What is your view as to why we are having this growth explosion and when can we expect to hear the results of your study?

Answer. The NEI has the lowest average competing research project grant costs at NIH. We believe that this low average grant cost is the direct result of NEI's long-standing emphasis on supporting research project grants (primarily traditional research projects (R01s) and first independent research support and transition awards (R29s)) rather than utilizing the more expensive NIH funding mechanisms. However, NEI grant costs have continued to increase, as have those of the NIH in general, and the number of competing research project grant awards that can be made within the available funding has continued to decline.

The NIH and others have attempted to determine the reasons for the increases in cost of biomedical research. In the case of the NEI, with its emphasis on research project grant awards, these reasons may differ from those for the NIH as a whole, and thus we believe a separate analysis is warranted. Our analysis will include: the number of investigators involved in the research; the total number of full-time equivalent positions supported; the level of effort of the principal investigator; the average salary of the principal investigator; faculty rank of the principal investigator; trends in the costs of supplies, equipment, and travel; and trends in the average direct costs requested, recommended, and awarded. We hope that when this analysis is completed, we will be able to identify the principal factors that have contributed to the increased costs of the typical NEI research project grant. We expect this study to be completed in the fall of 1990.

RETINAL DEGENERATION/TISSUE TRANSPLANTATION

Question. Dr. Kupfer, I understand that in the not too distant future we may initiate human trials to transplant tissue into the eye to correct for blindness, particularly that caused by macular degeneration. What can vou tell us about this and when do you expect human trials to begin?

Answer. A number of NEI supported laboratories are pursuing this important new line of investigation. To date, the key experimental results have been obtained using animals, principally rats. The results continue to demonstrate, often in dramatic fashion, the potential ability of transplanted retinal pigment epithelial cells to halt the photoreceptor degenerative process in the eyes of a special rat strain which has an inherited form of retinal degeneration. Many fundamental questions remain about this phenomenon, however. It is not clear, for example, whether it is the transplanted cells themselves, release of some critical factor or substance, or some other aspect of the surgical procedure which produces the effect. The specific mechanism must be understood to determine rationally the best treatment strategy for use in humans. The fact that retinal degeneration can be halted in this one rat strain will lead quickly to attempts to extend this general type of approach to other animal models of retinal degeneration. For the reasons outlined, we are still some time away from full-scale human trials of a "transplantation" treatment strategy.

SURGERY TO CORRECT FOR NEARSIGHTEDNESS

Question. Dr. Kupfer when do you expect you will be able to recommend the use of surgery to correct for nearsightedness?

Answer. Glasses or contact lenses can safely and predictably correct the refractive error of most nearsighted patients. Therefore, any surgical procedure to correct nearsightedness must meet extremely high standards of safety, effectiveness, and predictability before it can be routinely recommended. Results from a multi-center clinical trial sponsored by the National Eye Institute have shown that radial keratotomy, a surgical procedure in which radial incisions are made in the cornea, can reduce nearsightedness with few complications. The main drawback of the procedure is the difficulty in predicting the visual outcome in individual patients. Twenty-eight percent of eyes operated on in the trial remained nearsighted and 17 percent of eyes became farsighted. I would suggest that nearsighted patients, in consultation with their eye doctors, carefully consider whether surgical intervention is the best option for correcting their nearsightedness.

DECADE OF THE BRAIN

Question. Dr. Kupfer, I understand your Institute does more than $80 million of basic neurological research, almost as much as the Neurology Institute itself. Why is your Institute so heavily involved in basic neurological research and what benefits can we expect from this research with regard to the eye?

Answer. While the name of our Institute is the National Eye Institute, our research mission encompasses the study of disorders of vision and the mechanism of visual function. In order to do that, we must study not only the retina and the eye, but also the neural pathways in the brain that process information coming to and from the eye, including those that control the movement of our eyes from one object to another. Vision is thus the result of brain function that only starts with the eye.

Research on the visual system has always been in the forefront of basic neuroscience. This is partly because of the relative ease with which we can control the stimulus to the receptors (light) and the highly organized structure of the system from the eye through higher levels of processing in the brain. Vision scientists have made fundamental contributions to our understanding of the generalized nature of cortical structure. The visual system, like most other sensory systems, consists of both anatomical modules. This is reflected in segregation of visual functions such as motion perception into specific brain regions, and parallel pathways through the brain that serve general kinds of visual behavior, such as noticing the presence of objects in our environment versus concentrating on the detailed characteristics of those objects. Other neuroscientists have followed the lead of vision scientists in studying these properties in other sensory systems.

Another important area of research concerns molecules in the brain that encourage growth of optic nerve axons toward their target structures deeper in the brain. From such studies, we are learning that regeneration of damaged visual tissue is achievable under the right circumstances, something that was considered impossible only a few short years ago. Here again the visual system is serving as a leading model for advances in neural transplantation and regeneration. We hope that this very fundamental research will eventually have great payoffs in rehabilitation of deficits from stroke and trauma.

The eye, in particular the retina and optic nerve, is anatomically an extension of the brain and is, in fact, a particularly accessible part of it. In order to make progress toward our goals of preventing, treating, and rehabilitating diseases of the eye and visual system, we must understand the organization and function of this specialized neural tissue. Basic research on photoreceptors, for example, has led to an understanding of the mechanisms responsible for a variety of inherited diseases of the retina. Research on receptive fields of cells in the brain cortex of visually deprived kittens resulted not only in Nobel prizes for the scientists involved but a dramatic decrease in the age at which surgery is performed for crossed eyes in human infants in order to prevent amblyopia (lazy eye).

QUALITY OF LIFE

Question. As Americans are living longer, declining vision is fast becoming a primary concern for the elderly -- drastically reducing the quality of life for one of the fastest growing segments of the population. Doctor, what special initiatives are underway and/or on the horizon at the National Eye Institute to address this issue?

Answer. Although biomedical research is making great strides in preventing and treating eye diseases that affect our older citizens, many people inevitably experience irreversible losses in vision. The National Eye Institute has actively fostered research on low vision and its rehabilitation for many years, and the National Advisory Eye Council has just recommended establishing this area of research as a separate program to increase its visibility within the vision research community. In the current cycle of NEI program planning, there will again be a separate planning panel to address the needs of rehabilitation research. We are particularly interested in fostering collaboration between the eye care, basic vision research, and rehabilitation communities to ensure that the research has clinical, scientific, and everyday validity. Topics of special interest include characterizing better the nature of residual vision in low vision patients, determining the visual requirements of everyday tasks, such as driving and reading, and assessing systematically new and existing vision aids.

The National Eye Health Education Program is also addressing the needs of older persons. It is especially important that elderly citizens, who are at increased risk for many of the blinding eye diseases, be aware of the need for regular eye examinations to detect abnormalities at a treatable stage.

IDENTIFICATION OF VISUAL PIGMENT GENES

Question. What progress are we making in identifying the visual pigment genes and what are the major implications of this effort?

Answer. Dr. Jeremy H. Nathans, an NEI grantee at the John Hopkins University, has performed pioneering research over the last few years in identifying visual pigment genes in both cone and rod photoreceptor cells. The gene encoding human rhodopsin and full length cDNAs encoding bovine rhodopsin and three human cone visual pigments genes have been isolated.
The rhodopsin gene, for example, is now known to be located on human chromosome 3.

NEI grantees are now extending this fundamental research on the visual pigments to examine genes that may be defective in inherited ocular diseases. It is hypothesized that a gene encoding a structural or functional protein may be defective or absent in patients with retinitis pigmentosa or other inherited retinal diseases. The visual pigment genes, now identified, can be examined in these patients by molecular biological techniques. Two recent discoveries by NEI grantees are examples of this approach.

Investigations have recently determined that predisposition to acquiring an autosomal dominant form of retinitis pigmentosa (RP) is somehow linked to the genetic makeup of human chromosome 3. This finding prompted Drs. Thaddeus P. Dryja and Eliot L. Berson, NEI grantees, to ask, using recombinant DNA techniques, whether the rhodopsin gene was the specific gene affected in this condition. The answer to this question now appears to be yes. A change in a single amino acid (point mutation) is present in the rhodopsin gene of these individuals. This is the first specific gene defect to be found in any form of RP.

Dr. Nathans has studied twelve affected families of blue cone monochromasy, a rare X-linked inherited disorder of color vision, with the cloned visual pigment genes. Results showed that a specific region of the DNA of the red and green visual pigments, components of the retina which are necessary for color vision, are missing in these patients. Thus, the molecular basis of an inherited retinal disease has now been achieved and can guide studies of other inherited human color vision defects.

DECADE OF THE BRAIN

Question. The "decade of the brain" is an exciting time for biomedical research in light of research opportunities and potential technological developments in health care. To what extent is the Eye Institute involved in this biomedical agenda and what are the implications for individuals suffering from eye diseases and disorders?

Answer. Knowledge of how the visual system works depends on a clear understanding of how the brain works. The National Eye Institute supports research in many areas of neuroscience including the development and regeneration of the visual nervous system, investigation of the brain centers that underlie visual processing, and neuroscience models of how the visual parts of the brain function.

The development and regeneration of the visual system continues to be an active area of research. The high degree of structural order which characterizes the visual pathways makes them an ideal model for studying the development of the brain. Research is underway on factors that control the regeneration and development of the visual nervous system. The role of molecules that guide nerve regeneration or block it, as well as studies of the neuronal microenvironment continue to draw the attention of visual scientists. There has been a surge of interest in the array of growth factors that affect the nervous system, and much of this work could have direct application to an understanding of how to regenerate damaged brain tissue.

There is a renewed interest in higher level visual processing in the visual system. Visual neuroscientists have identified regions of the brain that are involved in the perception of color, form and motion. Groups of nerve cells in the brain have been identified that carry out perceptual decisions, which indicates that relatively small numbers of nerve cells in these brain centers are required for perceptual judgments. This research has been refined further by the application of computational models of brain function. These models have recently been able to make specific predictions about how visual centers of the brain work. Important interactions are occurring between visual and computational neuroscientists which will give rise to even more powerful models of how the brain functions in visual processing. More knowledge about the activity of these brain centers could help us in our understanding of the recovery from stroke and blindness.

NEARSIGHTEDNESS/RESEARCH AND ADVANCES

Question. Doctor, I understand that approximately 100 million Americans have vision difficulties related to refractive error -- that is nearsightedness, farsightedness, or astigmatism. What advances are we making in this area of research?

Answer. Myopia, or nearsightedness, is a developmental disorder in which the eye continues growth beyond the point where rays of light can be focused by the cornea and lens on the retina. Over the past several years, scientists have determined, through the use of bird and primate models, that eyes that receive blurred images or diffuse light experience this abnormal growth. Current research is investigating the biological mechanisms for this disorder. One very active line of research involves the process of accommodation, which is the change in the shape of the lens required to focus on near or far objects. It has been shown, for example, that the resting focus of the eye changes in the myopic direction after intense accommodative effort. Other research is looking at biochemical changes in the eye that accompany the development of myopia in animals. Epidemiological research is also now beginning to study the changing relationships of the optical components of the eye during development of both normal and abnormal vision.

One-third of the American population suffers from myopia and other errors of refraction. Our nation spends eight billion dollars annually for optical appliances and the eye care associated with their use. The development of a permanent cure for refractive error continues to be a major challenge and over a dozen surgical procedures are currently in the developmental stage. The National Eye Institute presently funds 12 research grants and a multicenter clinical trial in support of basic and clinical research on the surgical correction of refractive error.

Despite widespread interest in achieving normal visual function without dependence upon external devices, none of the present surgical procedures has gained widespread clinical acceptance. All the available techniques fail to achieve predictable outcomes. It is clear that refractive surgery cannot fulfill its promise until we gain a more fundamental knowledge of the mechanical properties of the cornea. Therefore, the NEI recently convened two workshops on corneal biophysics entitled, "Corneal Biomechanics and Wound Healing." We brought together cell biologists, biochemists, surgeons, engineers, and physicists to summarize the state of our knowledge in this field and to identify areas of research that need immediate stimulation. In the future, we will place high emphasis on funding projects designed to understand the dynamic response of corneal tissues to surgical intervention.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

INTRAMURAL RESEARCH INITIATIVES

Question. Dr. Kupfer, I note that the budget request includes an increase for your intramural research program of over 10 percent, yet your overall budget rises just over 4 percent. Would you describe for the Committee the research supported in the intramural program and the rationale for the increase?

Answer. The NEI intramural laboratory and clinical research program has seven components: the Clinical Branch, the Laboratory of Sensorimotor Research, the Laboratory of Molecular and Developmental Biology, the Ophthalmic Genetics and Clinical Services Branch, the Laboratory of Immunology, the Laboratory of Retinal Cell and Molecular Biology, and the Laboratory of Mechanisms of Ocular Diseases. This budget activity also includes the Biometry and Epidemiology Program.

Using a multi-disciplinary research strategy, NEI investigators conduct research to determine the causes of blinding and disabling vision disorders for such diseases as uveitis, diabetic retinopathy, retinitis pigmentosa, eye movement defects resulting from neurologic deficits, and maturity-onset cataract. A brief description of a cross-section of intramural research initiatives follows:

Uveitis

- By feeding laboratory animals antigenic protein, NEI researchers have been able to prevent experimentally induced uveitis, a severe ocular inflammation that can result in blindness. This autoimmune disease is sometimes difficult to control with immunosuppressive agents, and these agents often have serious side effects. Researchers will soon begin oral administration of the antigenic protein to uveitis patients in an effort to induce T-cells of the immune system to suppress the uveitis. A new therapeutic approach such as this would be highly beneficial.

Retinal Transplantation

- Using the techniques of molecular biology, NEI intramural scientists are neutralizing white blood cells that cause graft rejection. Work in this area may prove important in future methods for treating patients in whom retinal cells have degenerated or been destroyed. By transplanting living retinal cells into the back of the eye without inducing rejection, the researchers hope one day to restore vision that has been lost to disease.

Eye Control and Brain Function Relationship

- Research on the organization of rhesus monkey brain cells into functional circuits that control eye movements has contributed nearly all that is known about similar functions in the brain of man. Advances in mapping the circuits that underlie the generation of rapid, or saccadic, eye movements have been used to develop exact measures and a better understanding of a disease of this system in man, progressive supranuclear palsy. This model is being used to elucidate the factors affecting recovery of brain function which will be directly applicable to humans recovering from stroke.

Diabetic Retinopathy and Neuropathy

- NEI scientists have developed a precise model of human diabetic retinopathy in galactose-fed dogs. These studies clearly demonstrate that retinal vessel changes occur that are similar to those seen in humans. These changes occur because aldose reductase, an enzyme, converts the high levels of sugar in the blood to sugar alcohols in the cells of retinal vessels causing swelling and eventual breakdown. Treatment studies with aldose reductase inhibitors are being conducted to determine the earliest stage at which the disease can be arrested. Noninvasive methods for assessing aldose reductase activity in target tissues are being developed using nuclear magnetic resonance spectroscopy. These studies may have direct application in the control of the clinical complications of diabetes, particularly retinopathy and neuropathy.

Cataract

- Investigators studying the causes of maturity-onset cataract have found that certain oxidation reactions produce permanent and cumulative changes in lens proteins. In particular, oxidation of the amino acid, histidine, a component of all proteins, results in a cross-linking of the proteins that causes a loss of lens transparency. NEI researchers are developing lens cell culture systems to test potential anti-cataract drugs that would block the oxidation reactions or counteract their effects.

Gene Structure and Function

- Intramural scientists continue their research on the structure and function of genes vital to the normal development and transparency of the lens. These scientists have recently discovered that many of the major lens structural proteins, known as crystallins, are found at lower levels outside the lens, where they have additional nonstructural functions. These discoveries suggest that the crystallins have a metabolic as well as a structural role. The identification of DNA sequences that can direct the expression of a gene with lens specificity may one day permit genetic engineering in the visual system and bring us one step closer to gene therapy for certain eye diseases.

Retinitis Pigmentosa

- Researchers have been engaged in a study of a dog model of the blinding human disorder, retinitis pigmentosa. This group of diseases affects approximately 100,000 Americans, and is characterized by progressive loss of photoreceptors that may ultimately lead to blindness. These researchers have found that the affected dogs, compared to healthy dogs, have low levels of a particular polyunsaturated fatty acid called docosahexaenoic acid (DHA) in their plasma, suggesting that some other organ, probably the liver, is deficient in converting dietary fatty acid to the DHA needed for healthy photoreceptor function. The dog model provides an opportunity to determine whether dietary supplementation with DHA can prevent or arrest the progression of this blinding disease. The results of these studies may have relevance to humans because low blood levels of DHA have been found in certain groups of retinitis pigmentosa patients.

Biometry and Epidemiology

o The primary mission of the Biometry and Epidemiology Program is to plan, develop, and carry out human population studies concerned with the causation, prevention, and treatment of eye diseases and vision disorders. The program to evaluate new treatment strategies for diabetic retinopathy, a serious complication of that disease, continue to report significant findings. These studies are playing an important role in guiding clinical care of diabetes.

With regard to the budget rationale, the President's request allows for the continuation of research initiatives that are currently underway and includes support for built-in increases in services provided centrally, personnel expenses, research supplies and services, and animal care requirements.

RESEARCH TRAINING

Question. Dr. Kupfer, maintaining a strong research program at the Eye Institute is a goal I know we both share. Yet, I am troubled by the cut recommended in the Institute's training program. Do you expect to support the same number of training grants in FY'91 as in FY'90?

Answer. The President's budget request provides support for nearly the same number of training grants in fiscal year 1991 as in 1990. The distribution between individual and institutional research training awards is estimated to be as follows: 86 individual awards in both years, and for institutional grants, 31 and 27 respectively. This combined individual and institutional training effort will allow NEI to support nearly 254 trainees in fiscal years 1991 and 1990. It is important to note that these figures are estimates that are based on various assumptions, including the relative seniority of the postdoctoral fellows and trainees that are appointed. The actual number of trainees that can be supported will be determined when the assumptions are replaced with hard data.

Question. How is this possible with declining resources?

Answer. The fiscal year 1991 request provides approximately the same level of funding for training as the 1990 budget. As such, we estimate that nearly the same number of trainees can be supported.

NATIONAL INSTITUTE ON AGING

STATEMENT OF DR. T. FRANKLIN WILLIAMS, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next, the National Institute on Aging. Dr. Williams, delighted to have you with us.

We have your request for $248.94 million, a 3.96-percent increase. Again, welcome and please proceed.

HISTORIC TIME FOR AGING RESEARCH

Dr. WILLIAMS. Thank you, Mr. Chairman. This is very much a historic moment in time in the field of aging, not only because major advances in research are coming to fruition but also because we now have three subspecialties in geriatrics in the fields of family medicine, internal medicine and psychiatry. This indicates the widespread recognition of this area of knowledge and its application to care.

ALZHEIMER'S DISEASE

I want to touch on a few highlights in our research areas of special emphasis and priority. Certainly the greatest emphasis of our Institute is on the health crisis produced by Alzheimer's disease in older people. Over 4 million people in this country have this disease, and it is now imperative that we halt this growing epidemic through more research. I have previously said that we must have the goal of halting this disease within this century.

There are many lines of research that are quite promising, including advances in understanding the genetics that underlie some forms of this disease, the possible role of neurotoxic substances and infectious agents, and the possibility that Alzheimer's disease may be a widespread systemic disorder. For example, recent studies supported by our Institute show the amyloid changes characteristic of this disease are found in the cells of skin as well as brain. This may, among other things, lead to a simpler and more definitive diagnostic test which could save as much as $1 billion a year.

One of the most promising areas of research in my judgment is that on nerve growth factor which can influence the survival or regeneration of brain cells following injury. We plan within the next 2 years to begin clinical trials on nerve growth factor in Alzheimer's disease and other degenerative diseases.

PHYSICAL FRAILTY

A second area of importance is that of physical frailty and the role rehabilitative approaches play in restoring and maintain independence in older people, which is the greatest goal of all of us and all older people. Research emphasis is placed on the role falls, hip fractures, and diseases such as osteoporosis play in frailty and on efforts to restore function as well as prevent these problems. An overall related goal is that of health maintenance in older people and the key role of maintaining physical activity. Many studies now show the great benefits of maintained physical activity in maintaining health and independence of life in later years.

CELLULAR SENESCENCE

A third area of exciting research is that of cellular senescence and the genetic basis for the decline in cell proliferation. This work is done primarily with human skin fibroblasts, cell cultures from the skins of humans, which show that in prolonged cultures or in cells removed from older people, there are genes brought into action which then depress further cell proliferation. There are also now proteins that can be isolated and put into young cell systems to depress cell proliferation. Just in the last few weeks there have been reports of findings which show that one of the major oncogenes, the C Foss gene, is turned off in the cell lines of these late proliferating senescent cell lines. Another very recent report shows that there are genes, one of which has been identified on chromosome 1, which will also turn off an oncogene of this type. This provides a great opportunity to understand the aging process itself, plus the potential that some of these genetic findings have for opposing cancer growth.

PREPARED STATEMENT

Finally, special populations we continue our strong commitment to research on special populations of older people, including those in rural settings and various minorities, as well as worldwide comparative studies on populations and cultures. This year we will fund two centers on rural health and aging, and we plan to initiate a project on health and retirement as suggested by Congress.

Our fiscal year 1991 budget request is $248,938,000. I would be very happy to answer questions.

[The statement follows:]

STATEMENT OF DR. T. FRANKLIN WILLIAMS

The field of aging has increasingly attracted major scientific interest since 1974, when the National Institute on Aging was established. Over the past 15 years, there has been an unprecedented and exponential growth of new and exciting research opportunities. It is important to recognize that we are very much at a historic moment for the field of aging--a period marked by advances in new frontier research. A reflection of this historic development has been the establishment of three new subspecialties in geriatrics. Fifteen years ago it was difficult to find even a handful of medical schools in the country with a special focus on older adults. Today, the fields of internal medicine, family practice, and psychiatry are each establishing a subspecialty in geriatrics--reflecting a whole new level of scientific curiosity and capacity to conduct research on aging. This is further reflected by the significant growth of high quality research grants approved for funding.

The conquest of Alzheimer's disease (AD) remains the NIA's most important priority. Other continuing priorities include understanding of the basic mechanisms and characteristics of aging; promotion of health, effective functioning, and quality of life--including prevention or reduction of physical frailty; long-term care and caregiving; special populations including the oldest old, older persons in rural settings, and minorities; and training and career development in aging research and geriatrics.

Alzheimer's disease has brought on a health crisis of epidemic proportions. It is one of the most prevalent, devastating, and costly diseases of later life. Recently published data indicate that AD may be more prevalent than previously reported. It is now estimated that 4 million people have AD at an estimated cost of $80 billion a year. It is imperative that we halt this growing epidemic through further research.

While progress is being made in understanding AD, we do not yet know the cause(s). Studies on the genetics of AD have shown that there is a linkage between chromosome 21 and the early onset familial form of AD. Recently, studies have begun to yield results that establish an association between chromosome 19 and late onset AD. Other leads on the possible cause of AD suggest that aging may increase susceptibility of the nervous system to toxins and other environmental perturbations. There is growing evidence that neurotoxins cause specific nerve cells to die, thus contributing to the etiology of AD.

Preliminary evidence has indicated that AD may be caused by an infectious agent. Confirmation of these results through additional research is an urgent need. Such research is critical before we can be sure whether some cases of AD have an infectious origin. A multi-center replicative trial is currently under consideration to test this hypothesis.

An abnormal protein, amyloid beta-protein, which is associated with the hallmark of AD brain pathology, has now been found in non-neuronal tissues such as the skin, subcutaneous tissue, and intestine. These data suggest that AD could possibly be a widespread systemic disorder, and support other findings indicative of a metabolic defect in AD. Research in this area suggests that abnormal processing of the amyloid precursor protein could be a consequence of this disease and produce some of the cellular events associated with AD.

Researchers are now finding ways to slow down or prevent cell loss by stimulating the brain with chemicals used to promote cell growth during development. Since AD involves massive cell death, such work has important implications for developing treatments. More specifically, it has been shown that nerve growth factor (NGF) can be administered to targeted areas of the brain in experimental animals such as mice and will produce nerve growth and improve function. A goal is to determine the potential use of NGF and similar substances to prevent or correct cell loss in Alzheimer's and other degenerative diseases.

In relation to the possibility of treating and minimizing the effects of AD through use of medications, the clinical trial on the efficacy and safety of tetrahydroaminoacridine (THA) is proceeding as planned, with the expectation of definitive answers within this fiscal year. There are, moreover, additional AD drugs emerging as candidates for clinical trials.

Understanding the basic mechanisms of aging is an important step in the process of identifying interventions to delay or modify human aging. NIA is introducing a research initiative to determine the mechanisms by which lower consumption of calories dramatically lengthens life span and prevents age-related diseases, such as cancer, in experimental animals. Learning these mechanisms can reveal how these age-associated changes could be prevented or delayed in humans. Researchers supported by NIA are studying age-related changes in cell proliferation--why certain cells in laboratory chemical cultures have a limited life span. The results of one such study just reported this January uncovered new clues about the molecular basis of cellular senescence. A repressed gene was identified, along with a reduced amount of a protein considered essential for normal cell division. Such results have potentially major ramifications not only for understanding underlying mechanisms of aging but in providing new ideas about cancer intervention as well. Whereas in aging, cell proliferation slows, in cancer it grows out of control; cellular mechanims regulating aging may potentially be influenced to regulate various cancers.

A major goal of the NIA is to help older people maintain an independent life style and to reduce the risk of needing long-term care. Physical frailty significantly diminishes the ability to conduct common activities of daily living, and increases risk of falls and hip fractures. Preventive and rehabilitative strategies, however, show strong promise for reducing frailty and injuries. For example, a large scale study has shown that a comprehensive falls prevention program can significantly reduce the number of falls in older people. Other studies have shown that older persons who fall have weaker leg muscles than others of the same age who don't fall, while related studies show that exercise can dramatically restore leg strength even in very old frail 90-year-old nursing home residents. In 1990, NIA and the National Center for Nursing Research will jointly initiate the Frailty Clinical Trials, to test interventions to reduce physical frailty and its consequences in older persons.

Another aspect of the frailty initiative is NIA's osteoporosis program which has a special focus on aging-associated aspects of this disease. Because bone loss is almost universal with increasing age, NIA supports research to identify age-associated processes responsible for osteoporosis, and to develop prevention and treatment strategies based on modifying them. Such strategies offer the promise of fundamental major progress in preventing or curing this disease. NIA especially emphasizes osteoporosis in advanced age, when it is most severe and causes the most severe disability and mortality, especially from hip fractures. Because many aging processes are modifiable by exercise, nutrition, and other factors, NIA is placing increasing emphasis on testing interventions against osteoporosis. Interventions developed through NIA's frailty and osteoporosis initiatives could result in major reductions in future long-term care needs.

Geriatric rehabilitation is an area of increasing NIA emphasis. In May 1989, NIA issued a program announcement encouraging research on biomedical and psychosocial aspects of rehabilitation for older persons. In 1990, the NIA will solicit applications for Special Emphasis Research Career Awards in Rehabilitation and Aging. These awards will provide five years of career development support aimed at increasing the small number of researchers with expertise in both aging and rehabilitation. Rehabilitation looked at within the context of aging will also add significantly to reducing the burdens of long-term care.

NIA intramural researchers and researchers supported in other settings are studying the extent to which exercise regimens can forestall or ease age-associated physiological decrements, inhibit the development of diseases, and increase longevity. Accumulating evidence suggests that expected age-associated changes in such physiologic parameters as blood glucose tolerance, skeletal muscle strength, and cardiac measures occur to a lesser extent--if at all--in physically fit older persons. Increased research attention is needed on the problem of cardiovascular disease in older persons. Despite progress in preventing cardiovascular disease in middle age, important questions remain about the effectiveness of current prevention strategies for older persons. Evidence indicates that new strategies, based on increased understanding of the relationship of aging to vascular disease, will be needed for optimal prevention of this major cause of death and disability among older persons. For example, recent studies have shown the high value of stress tolerance tests, using electrocardiograms and thallium scanning in predicting the likelihood of a coronary event in the next 4-5 years--essentially the same high confidence in not having a coronary event in men aged 60-69 as in those age 40-59, if the stress test is normal.

The NIA has a strong commitment to research on the health and well-being of special aging populations such as the oldest old, older persons in rural settings, and minority groups in the United States, and older populations in cross-national and cross-cultural settings throughout the world. The NIA is studying the differences of life expectancy between blacks and whites, including behavioral and life-style antecedents. Ongoing epidemiological studies are examining variations in different ethnic and cultural groups in such topics as dementia, skin cancer, bone density, hypertension and diet, diabetes, sickle cell trait, and vision and hearing. Other studies are addressing intellectual functioning and family structure.

Older rural residents face many problems which affect them specifically because they live in rural areas. Problems of access to and affordability of medical and social services are particularly important for these individuals. Rural areas generally support a narrow range of services, have a higher proportion of poor and medically uninsured individuals than do urban areas, and face a continuing problem in recruiting and retaining health care professionals. Rural residents typically live at some distance from physicians, hospitals, and other social services, and do not have access to public transportation. The NIA has initiated a program of center grants on the health and well-being of older rural populations, and expects to fund two such centers in FY 1990.

The health care needs of a growing population of older persons will require increased numbers of geriatricians and other health care providers with training in geriatrics. These growing needs require more individuals capable of conducting research in geriatrics and training future geriatricians. In response to this need, the NIA has established the Claude D. Pepper Geriatric Research and Training Centers program. These centers are designed to enhance collaborative efforts in geriatric research and provide training and career development for academic geriatricians who will increase academic leadership in the field nationwide. Two centers have been funded.

NIA has a strong and growing interest in geriatric pharmacology. Older people commonly take several medications, which frequently interact to produce adverse effects. Yet too little is known about drug metabolism, pharmacodynamics, appropriate dosages of medicine needed by older people, or the causes of adverse drug reactions in older people and how to prevent them. Relatively few drugs have been thoroughly evaluated in older persons. Considerable difference in a drug's half-life can be observed in comparisons between young adults and older persons, indicating the potential need for very different prescribing patterns for older persons. The NIA plans a broad spectrum of basic and clinical research on the use and effectiveness of medications in older people.

Older people are, unfortunately, sometimes viewed as an unproductive drain on society; in reality they are an untapped national resource. Though older people may spend two to three decades of their lives in retirement, many want and are capable of continuing some form of productive activity. Extending productivity into the later years has obvious ramifications for national policy, yet little is known about how current work and retirement trends affect the physical and psychosocial functioning of aging individuals, or the degree to which they result in losses of productivity for society and older people themselves. Current NIA research on these issues will be supplemented by initiation of the longitudinal Health and Retirement Survey planned for 1990.

Mr. Chairman, the 1991 budget request for this Institute is $248,938,000. I will be happy to answer any questions.

BIOGRAPHY OF DR. T. FRANKLIN WILLIAMS

Birthdate: November 26, 1921 - Belmont, North Carolina

Education: B.S., University of North Carolina, 1942; M.A., Columbia University, 1943; M.D., (Cum Laude) Harvard Medical School, 1950

Professional History: 1983 to present, Director, National Institute on Aging, NIH, 1983, J.Lowell Orbison Alumni Distinguished Service Professor; 1982-1983, Director of the Geriatric Unit, Monroe Community Hospital, Rochester, N.Y.; 1980-1983, Co-Director, Center on Aging, University of Rochester Medical Center; 1968-present, Professor of Medicine and of Preventive, Family and Rehabilitation Medicine, University of Rochester; 1968-1982, Medical Director, Monroe Community Hospital, Rochester, N.Y.; 1977, L.S. Mcleod Visiting Professor of Geriatric Medicine, University of Adelaide and South Australia Postgraduate Medical Education Association; 1956-1968, Instructor to Professor of Medicine and of Preventive Medicine, University of North Carolina; 1954-1956, Fellow in Medicine, University of North Carolina; 1953-1954, Assistant in Medicine, Boston University; 1953-1954, Senior Resident Physician, Boston Veterans Administration Hospital; 1950-1953, Intern and Assistant Resident Physician, John Hopkins Hospital; 1942-1943, Assistant in Chemistry, Columbia University.

Military Service: 1983 to present, Assistant Surgeon General, U.S. Public Health Service; 1943-1946, Communication Officer, U.S. Naval Reserve, active duty.

Societies and Associations: American Association for the Advancement of Science (Fellow); American College of Physicians (Fellow); American Federation for Clinical Research; American Public Health Association (Fellow); American Society of Human Genetics; American Geriatrics Society; American Diabetes Association; Society for Experimental Biology and Medicine Rochester Academy of Medicine; New York and Monroe County Medical Societies; Gerontological Society of America; New York State Public Health Association; Association of American Physicians; Institute of Medicine, National Academy of Sciences; The Royal Society of Medicine; and Academia Medicorum Litteratorum.

Honors and Awards: Phi Beta Kappa; Alpha Omega; Sigma Xi; Member, Institute of Medicine; Diplomate, American Board of Internal Medicine; Diplomate, National Board of Medical Examiners; Markle Scholar in the Medical Sciences; Special Fellow, Department of Physiocoloy, Vanderbilt University; Honorary Member, American Academy of Orthopedic Surgeons; and Honorary Doctor of Science, Medical College of Ohio.

Publications: Author of over 131 publications in journals and books.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. Thank you very much, Dr. Williams. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

NEW TREATMENTS FOR ALZHEIMER'S DISEASE

Question. Dr. Williams, I was surprised to learn 12 to 16 new drugs to treat Alzheimer's disease are now being tested in Europe. But in this country we only have one clinical trial underway on THA. Are we being too conservative in this country in launching human trials and tests of new drugs for Alzheimer's disease?

Answer. The race to find a definitive treatment for Alzheimer's disease (AD) is on. It has been estimated by a recent survey that over 100 trials, controlled and uncontrolled, have been conducted with drugs for AD in the United States. Many of these trials were small and uncontrolled, but the extent of the search is clear. With enough resources and continued commitment from the scientific community, it should be possible within the next 5 to 10 years to develop an agent that will provide some relief to the patients from the debilitating cognitive changes of AD.

As many as 40 existing drugs, compounds, and biologicals have been proposed or suggested as treatments for Alzheimer's disease. Presently, there are 16 initial or preliminary studies of drugs for AD underway in the United States, some of which are likely to indicate the need for full scale clinical trials. The speed and magnitude with which the formal trials themselves can be completed will be a factor of available funds. The National Institute on Aging is supporting the one major ongoing clinical trial, of tetrahydroaminoacridine (THA) which will provide information on the safety and effectiveness of THA later this year.

At the moment, the only chemical compounds on the horizon that offer possible hope of curing or of altering the course of the illness permanently are the natural products, nerve growth factor. The drugs proposed for trial may offer temporary interim relief; therefore, it is important that the drugs do not cause harm to the patients. The degree of acceptable risk is continually reevaluated against the potential benefits. As more promising agents are identified, patients, families, scientists, and regulatory agencies will, no doubt, further assess the speed with which the agents are brought to clinical trial, and ultimately to the market place.

PREVALENCE OF ALZHEIMER'S DISEASE

Question. A recent report from the community study in East Boston indicates that the prevalence of Alzheimer's disease may be greater than previously thought with perhaps as many as 47 percent of those people over age 85 affected. These numbers are very concerning. What are the immediate and long-range implications of these data?

Answer. The report of the prevalence of Alzheimer's disease by Dr. Denis Evans and colleagues has caught the attention of the general public as well as the scientific community. The paper did, indeed, reveal higher prevalence rates at all age groups than previous investigations. The immediate implications of these data, when extrapolated to the United States population, are that the extent of AD in our population is much greater than previously appreciated. If it is assumed that the rates from East Boston accurately reflect the experience of the rest of the United States, then as many as 4 million people may already be suffering from this disease.

Alzheimer's disease is clearly most common in very old persons, those over 85 years of age and older. The numbers of people over age 85 are growing faster, and therefore, the number of individuals afflicted with AD will continue to increase. The immediate and future implications of these trends will have a major impact on the families involved and on health-care costs and the resources necessary to take care of these increasing numbers of people.

CAUSE OF ALZHEIMER'S DISEASE

Question. Dr. Williams, current theory has it that there is no single cause of Alzheimer's. The leading theories are that it is caused by a toxin, it is some sort of defect in the metabolic process, it may be caused by some chronic infectious agent, and of course, genetics also plays a role. What progress is being made in research to better determine the cause of this disease?

Answer. At present no single factor adequately can account for AD. Many scientists believe that AD is caused by the interaction of several etiological factors. The most promising leads on the cause of AD come from the recent successful identification of the abnormal proteins that comprise the hallmark lesions, namely, the plaques and tangles which accumulate in the brains of AD victims. Their association with AD pathology has sparked renewed interest in the synthesis and function of normal counterparts of these proteins. Scientists believe that AD results in a defective processing of these proteins, resulting in their accumulation in plaques and tangles. The way this is brought about is not yet clear. It is also noteworthy that the amyloid changes have not been found in the fibroblast cells from skin biopsies of AD victims, indicating that this is indeed a system disease.

Several lines of research point to defects in protein turnover and activation, which play central roles in brain function. The same mechanisms which cause the accumulation of specific proteins are likely to be involved in synaptic loss and neuronal cell death, which are the most serious consequences of the disease. A variety of causes, including metabolic defects, genetic predisposition, environmental toxins, and infectious agents, may funnel into similar or identical biochemical pathways to produce the symptoms and pathology that we recognize as AD. These hypotheses are currently the subject of intense experimental investigation.

DIAGNOSIS OF ALZHEIMER'S DISEASE

Question. Dr. Williams, while there is no absolutely perfect diagnosis for Alzheimer's, without examination of the brain tissue, the diagnostic techniques have much improved. As you know we have approximately 150,000 new cases of Alzheimer's disease each year. Each case costs approximately $1,500 to diagnose and because of the trauma of the diagnosis, most people seek a second or third opinion. Needless to say, we are spending several hundreds of millions of dollars on redundant diagnosis because of the lack of precision of the current technique. Do we have a protocol for diagnosis that you are recommending we use nationwide and when can we expect it to be adopted in the practice of medicine across the country?

Answer. On July 6-8, 1987, a Consensus Development Conference on the Differential Diagnosis of Dementing Diseases was held at the National Institutes of Health. The Panel made a number of recommendations on the initial examination of a patient presenting cognitive changes and on the diagnostic tests to be performed. The Consensus Development Panel stated that "the best diagnostic test is a careful history and physical and mental status examination by a physician with a knowledge of and interest in dementia and the dementing diseases." Laboratory tests and imaging studies should be based upon the findings of the physical and mental status examination and the history provided. The recommendations were conservative and reflected the concern of the Consensus Development Panel to avoid subjecting the patient and family to unnecessary tests ordered simply out of routine, discomfort, inconvenience, and excess costs.

The Consortium to Establish a Registry for Alzheimer's Disease (CERAD) has been working to develop the minimum battery of neuropsychological, neurological, neuroradiological, and neuropathological studies needed for the accurate diagnosis of AD and for subsequent follow-up of patients. Twenty U.S. universities are cooperating in the CERAD standardization study in addition to several foreign institutions. The results of CERAD will result in further specification and refinement of the appropriate investigations leading to a diagnosis of AD.

One of the critical research and clinical needs is the development of an easily attained biological marker that reliably and validly detects Alzheimer's disease even in the very early stages. A biological maker developed from urine, blood or small skin samples, for example, the amyloid deposits in cells from the skin, offers the possibility of substantial cost savings in the reduction of numbers of second and third evaluations sought by patients and families.

Additionally, it is necessary in clinical drug trials to be reasonably confident of the underlying pathology affecting the patients, and AD in the early stages is still occasionally difficult to diagnose. Therefore, an accurate biological marker that detects early disease would allow the more confident incorporation of less deteriorated patients into clinical drug trials, when theoretically the chances of improvement are best.

HEALTH AND RETIREMENT SURVEY

Question. Dr. Williams, the Committee, in its report accompanying the FY 1990 appropriations, urged your Institute to begin a health and retirement survey. This survey would update data, now 20 years old, by establishing a cohort of people and tracking them through the aging process. I would like you to tell the Committee when you expect this survey effort to begin, and outline for us the benefits we can expect from the survey.

Answer. The Health and Retirement Survey will begin in September 1990. We expect that the design and planning phase should last about a year. Depending upon the extent of available funding, the baseline interview is likely to be done in 1991 and 1992, with the first results available in late 1992 or early 1993 and continuing results available in each subsequent year.

Despite changes in the provisions of the Social Security system that favor later retirement, older workers, especially men, are leaving the labor force earlier. For example, in 1967, 78 percent of men aged 60-64 were working, while in 1986 only 55 percent of men in this age group were working. Unfortunately our understanding of this phenomenon, which has great significance for the aging and well-being of individuals as well as for the society, is seriously hampered by the lack of reliable and complete data on the retirement process. Little is known, for example, about the current role of health factors in these decisions.

The economic impact of labor force participation rates for older workers is immense. A very rough and preliminary calculation indicates that if the labor force participation rate for those aged 55 and over in 1987 was the same as it was in 1967, there would be an increase in total earnings and fringe benefits added to the GNP of over $120 billion per year. There are obviously many limiting external factors which make this gain unlikely to be realized. Many workers have obviously decided to trade leisure for earnings. However, results from the just released Harris Poll Survey provides information on those aged 50-64 who would like to re-enter the labor force. Nearly 2 million said that they would like to get jobs. If only 1.1 million of these who are the prime candidates for new jobs, that is, the highly motivated and qualified who would accept available salaries and working conditions and who are healthy enough to work, are included in the calculation, then the GNP would rise by about $14 billion per year with increased tax revenues over $2 billion per year.

The research based on this survey will provide the necessary information base for federal and private sector retirement policies. It will allow us to evaluate current policies aimed to allow those who wish to work to have the maximum opportunity to do so. Decisions on retirement also have an impact on the two or three decades of the lives of the retirees in terms of their activities and their financial resources for their retirement years and health and long term care. The study will also allow us to understand how people are making these decisions today in light of increased longevity and risk for long term disability.

GERIATRIC HEALTH SPECIALISTS

Question. Dr. Williams, it has been a concern of this Committee for some years that we have an inadequate number of geriatric health specialists both in the research community and the direct care community. I was pleased to hear that three fields of medicine, this past year, established aging sub-specialties. To assist in this matter, the Committee asked NIH to establish one additional Geriatric Research and Training Center during FY 1990. Tell us what progress is being made in establishing this center and what general progress is being made in increasing the supply of geriatric health care specialists?

Answer. As you point out, the recommendation for centers of excellence comes at a time of historic opportunity for geriatrics in the U.S. with the three medical fields of internal medicine, family practice, and psychiatry establishing sub-specialties in geriatrics. Nearly every medical school in the U.S. is reexamining its curriculum in geriatrics. Thus the field is both ready for, and in need of, the expanded number of academic leaders who could be trained in these centers. Once trained, these academic geriatricians will establish new research and training programs and provide models of excellence in clinical care for the training of additional geriatricians.

The Health Omnibus Programs Extension Act of 1988 specifically authorizes NIA to make grants for centers of excellence in geriatric medicine. Accordingly, the National Institute on Aging (NIA) created the Claude D. Pepper Geriatric Research and Training Centers program. NIA is coordinating this program with the Health Resources and Services Administration to ensure that the two agencies' geriatric career programs complement each other rather than overlap.

The first NIA Claude D. Pepper Center was funded in FY 1989. Congress provided funds for one additional Center in FY 1990 and, recently, a second Center grant was made. There are an additional five high quality applications that could be funded and more applications are expected to be received this fiscal year.

The supply of geriatric health care specialists is slowly increasing, although at a rate inadequate to meet the needs of our rapidly expanding population of older persons. The shortage of academic geriatricians continues to limit the training of needed geriatric specialists. Creation of additional Claude D. Pepper Centers will allow the training of increased numbers of academic geriatricians essential for the training of clinical geriatricians available to provide services to older people.

THE OLDEST OLD

Question. Dr. Williams, as you know, we have approximately 3 million people in this country who are now 85 years old. By the middle of the next century we can expect to have 25 million of these oldest old. However, if people adopt healthier life styles and advances continue in medicine, we may well have 40 to 60 million people over 85 years of age. The country now spends $60 billion on health care services, both private and public funds, to support this group of the oldest old. What do you believe are the health care cost implications of this ever expanding cohort of those 85 years old and older?

Answer. The population over age 85, the oldest old, is regarded by the Census Bureau to be the fastest growing age group in the nation. However, a number of researchers have developed forecasts that far exceed the Census Bureau's high range projections for the middle of next century. One of these projections, using a modelling or simulation method, has indeed forecast that healthier life styles, such as greatly reduced smoking, hypertension, cholesterol, etc., could plausibly result in some 40-60 million people over age 85 in year 2050 or 2060. It is important to remember that this is an extreme, and not necessarily the most likely projection.

The implications for health care costs are astronomical since those age 85 and older have the highest morbidity burden of all groups and are the greatest consumers of both health care and federal benefits for the aged, in part because they also have the highest level of impoverishment.

There are many implications. First, the increase due to population changes alone will be considerable. Using this example, major Federal benefits for those aged 80 and older have been estimated to be about $62 billion in 1984 dollars, while in the year 2000 the expenditures are predicted to jump to $83 billion in 1984 dollars.

Second, the actual impact of this dramatic demographic change will be modified by the extent to which active, or healthy, life expectancy increases proportionately with disabled life expectancy. If the period of disabled life expectancy increases more rapidly than the period of active life expectancy, the cost effects will become more severe. Whether or not this happens will depend upon our ability to discover the risk factors for long term disability and institute effective prevention and rehabilitation programs. It is urgent that we find the answer through research to the major disabling conditions, including Alzheimer's disease, cardiovascular disease, osteoporosis with hip and other fractures, osteoarthritis, and losses of vision and hearing.

Third, it will become increasingly necessary for older people to retire later to build up sufficient financial reserves in order to minimize the chance of exhausting their financial assets. Later retirement would also allow older individuals to place larger reserves in health, long term care and life insurance plans for both themselves and their spouses. Since many of the oldest old outlive their spouses and other social supports, special care provisions will often need to be made for this group.

Question. Must we expect a fiscal crisis in providing services for this category of people, or can we realistically expect them to be healthier in the future and require fewer services?

Answer. There are divergent opinions about the likelihood of the oldest old being healthier or sicker, as a group, in the future. The National Institute on Aging initiative on the oldest old includes a component on forecasting active and life expectancy. A number of conferences on this topic have been held, with the Compression of Morbidity Among the Oldest Old to be held in March, and results from national surveys such as the National Long Term Care Survey and the Longitudinal Survey on Aging are only just beginning to become available. In order to answer this question, new cohorts would need to be inducted into these studies since those who are just entering into this age group may be very different, for example, more highly educated, than those who were 85 and older in 1984 when the Longitudinal Study on Aging started. Unless more modifiable risk factors for disability among the oldest old can be discovered, and interventions developed, we should expect a fiscal crisis.

WHY WOMEN LIVE LONGER

Question. Dr. Williams, there are a number of reasons women live longer; lifestyle and stress are among these reasons. But genetics plays a significant role in determining that women do live longer. What is research showing with regard to the genetic factors as to why women live longer?

Answer. The most obvious genetic difference is due to the expression of genes which direct and control the synthesis of the sex steroid hormones. These in turn are linked to the expression of genes coding for proteins involved in the metabolism of cholesterol. Female sex steroid hormones raise levels of HDL-cholesterol and lower those of LDL-cholesterol, whereas male sex hormones have the opposite effect. Because high LDL-cholesterol level (the male pattern) is a risk factor for heart disease, heart disease plays a major role in the current longevity gender gap.

Other phenomena are also thought to contribute to the longevity gender gap, although the evidence is weaker. These phenomena include a more robust immune system in later life in females, and the fact that women normally have two copies of every gene whereas men have only one copy of genes found on the X-chromosome. Furthermore, one unpublished study suggests there may be a life-shortening genetic region on the Y-chromosome. Unfortunately, we don't yet have enough data to conclude unequivocally that these factors contribute substantially to the longevity gender gap. Finally, in order to assess the role of genetics in explaining the gender differential in longevity, it is necessary to control for the interacting influence of social, behavioral and environmental factors, which clearly impact on the longevity of males and females to a different extent in our society. Research is needed to sort out the relative importance of all of these genetic and psychosocial factors.

ETHNICITY OF ALZHEIMER'S DISEASE

Question. Last year you indicated that two programs within your Institute were in the process of establishing a series of cross-cultural and cross-national research projects on the epidemiology of Alzheimer's disease and related dementias. These studies were to focus on populations of Asian, Pacific, European, and Black ancestry. What is the status of these research projects? Could you tell us the ethnic breakdown of Alzheimer's victims in the United States?

Answer. Older people in the United States, perhaps more so than in many countries, are an extremely heterogeneous group. They come from many ethnic groups and have an enormous number of different lifestyles, experiences and exposures. We do not know how any of these factors are related to the likelihood of developing Alzheimer's disease. It is not yet clear whether different subgroups of older people have differing rates of AD or whether AD rather uniformly affects the older people. Understanding of the distribution of AD in the United States is still in its infancy. It is not possible at this time to project the ethnic breakdown of AD victims nationwide.

However, some preliminary data from Duke University suggest that rates of AD may be high among African-Americans, and especially among African-American women. This information is not yet sufficient to discern if the causes involve genetic, educational, socio-cultural, or methodological factors. By contrast, preliminary evidence suggests that AD is quite rare in older persons in central Africa.

Also, preliminary findings among Japanese-American men living in Hawaii suggest that in this group Alzheimer's disease may occur at lower rates than have been found among older persons of European ancestry.

Epidemiologic research at three diverse sites in the continental United States has also demonstrated that substantial differences in prevalence rates of cognitive impairment and dementias do occur among communities. Although such variation may be partly attributable to genetic and/or environmental factors, it appears that major differences can also reflect community-specific socio-cultural and health care factors. Such factors may be powerful determinants of where the mildly or moderately impaired person lives. Depending on family and community resources, the person who becomes impaired may remain in the community, may move to an institution in the same or different community, or may move to another community. It is essential to discern between differences in rates of impairment that are due to factors determining where an impaired person lives, and factors directly influencing the development of impairment.

A major effort just now getting underway in Hawaii is aimed at an accurate assessment of rates and patterns of dementia among older Japanese-American men. A great deal of care will be taken in this study to ensure that its findings can be compared with other studies that are being or have been conducted in Japan, Taiwan, and the Continental United States.

A very important gap in our knowledge is the age-specific prevalence and incidence of AD in Spanish-speaking populations in the United States. A major investigation is now underway in New York City of the experience of blacks, whites, and Hispanics who are primarily immigrants from the Dominican Republic. Several other studies are also developing screening instruments that are appropriate for older Hispanics and materials explaining AD to Hispanic families and caregivers. The combination of a number of efforts aimed at special populations will yield the information needed to estimate the ethnic breakdown of AD in the United States. T' NIA is also, in conjunction with the World Health Organization Special Program of Research on Aging, developing an epidemiological study of dementias and Alzheimer's disease in five countries, including Spain, Malta, Nigeria, Canada, and Italy. This study will provide important new data on the prevalence of AD and other dementias in very different populations and cultures worldwide.

FRAILTY CLINICAL TRIALS

Question. In your testimony, you noted that NIA, in collaboration with the National Center for Nursing Research, will initiate the Frailty Clinical Trials in FY 1990 to test interventions to reduce physical frailty and its consequences in older persons such as developing rehabilitation strategies to reduce disabilities and long term care needs in older persons and developing promising new directions for improved treatment of osteoporosis. What will be the long run impact of these trials and will all promising interventions be tested?

Answer. As I noted at an October 1989 briefing requested by the U.S. Senate and House Committees on Aging, the Frailty Clinical Trials can have a major impact on dependence and long term care needs. They will test interventions that could significantly reduce physical frailty, that is, severely impaired strength, mobility, balance, and endurance, which lessen millions of older persons' abilities to live independently and contribute to falls and disabling injuries such as hip fractures.

The trials will test interventions to reduce physical frailty and associated long term care needs and injuries. Interventions include leg strengthening, balance and flexibility training, other rehabilitation strategies, nutritional interventions, fall and hip fracture prevention programs, and environmental/behavioral factors. Of the 42 proposals received, 12 were very highly rated but only eight will be funded due to budgetary limitations. Very strong unfunded proposals deal with physical therapy upon hospital discharge, hospital and nursing home physical therapy/rehabilitation regimens, and a sophisticated and unique exercise rehabilitation program.

It is critical to note that the Frailty Clinical Trials will test only a segment, albeit a very important one, of potential interventions against frailty. Because of the huge scope of this problem, NIA has organized a comprehensive long range research program aimed at continuing reductions in frailty and the care burdens it imposes. Other components of NIA's frailty research program include:

o Geriatric Rehabilitation. Millions of frail older persons could be restored to greater independence by rehabilitation, but better techniques are needed, especially for the 200,000 hip fractures occurring each year in older persons. Besides its Frailty Clinical Trials initiative, NIA has solicited proposals for biomedical and psychosocial research needed to achieve the enormous potential of geriatric rehabilitation. In 1990, NIA will also address a serious need for researchers with combined expertise in rehabilitation and aging by introducing special research career awards in this area.

o Geriatric Assessment. A recent NIH Consensus Conference panel noted the value of geriatric assessment in improving health outcomes and reducing health costs, and recommended research to improve assessment strategies further. Such strategies are crucial for improved long term care eligibility and reimbursement policies, since they could identify persons with treatable or preventable disabilities, for whom proper treatment and services could reduce long term care needs. Several approaches are ready for testing.

o Frailty in Minorities. Genetic, psychosocial and environmental factors affect risks for disabling diseases and abilities to cope with frailty and its consequences. To develop effective strategies to reduce frailty and disability among minorities, we need to learn more about the effects of these factors in different groups.

o Improving Medication Use Among Frail Older Persons. Geriatric patients often take several drugs whose side effects worsen frailty by impairing balance, orientation, and daily activities. Congressional hearings have highlighted severe health problems and costs due to poor drug prescribing for older persons. NIA has issued a Request for Applications for research to provide solutions to this problem. About 100 applications are anticipated, at least 25 of very high quality.

o Urinary Incontinence (UI). UI afflicts five million older Americans, and causes over $10.3 billion per year in health care and related costs. UI is a serious cause of disability and long term care needs among frail older persons, afflicting half of nursing home residents. NIA's UI research program includes both biomedical and behavioral approaches and has produced significant advances in treatment, but only a fraction of the potential for improvement. A 1988 NIH Consensus Conference recommended a major research initiative on UI. NIA's 1989 solicitation for proposals in response to these recommendations has engendered considerable interest.

o Fundamental Progress on Chronic Musculoskeletal Diseases and Disorders of Gait and Balance. Physical frailty would be dramatically reduced by better treatments for degenerative diseases which impair physical functioning among older persons. NIA has established a major osteoporosis program, focused particularly on preventing hip fractures. Clinical trials are now feasible in this area. Opportunities for progress against osteoarthritis, degenerative muscle conditions, and age-related disorders of gait and balance also merit increased research.

Progress in the above areas should lead to major reductions in dependence and long term care needs of older persons.

Question. In your professional judgement, what would be the appropriate level of support for these studies?

Answer. In my professional judgement, to adequately support the Frailty Clinical Trials, $5.5 million per year for three years is needed. This would allow funding the twelve best sites, each of which offers a unique contribution. Since $2.9 million will be awarded for limited funding of eight sites in FY 1990, an additional $2.6 million in FY 1991 would be needed for full funding of all twelve sites.

As I noted, the Frailty Clinical Trials are part of a comprehensive NIA research program on frailty, which includes the additional areas listed above. Current support for these is approximately $25 million per year. Based on present research needs and opportunities, additional appropriate support for these areas would be $3 million for geriatric rehabilitation, $3 million for geriatric assessment, $2 million for frailty in minorities, $6 million for improved medication prescribing, and $5 million for urinary incontinence research.

The total appropriate increment in support for these areas, plus the Frailty Clinical Trials, is approximately $21.6 million. Though substantial, this is but a small fraction of likely health and cost benefits which would result from major reductions in physical frailty and long term care needs over the next decade.

GERIATRIC RESEARCH AND TRAINING CENTERS

Question. How many Claude D. Pepper Geriatric Research and Training Centers has NIA funded? How many effective centers could be funded an this time?

Answer. There are currently two NIA Claude D. Pepper Centers. One was funded in FY 1989. Congress provided funds for one additional Center in FY 1990, which was recently funded. At least ten Centers will be needed to train the required number of academic geriatric leaders. For this reason, NIA has announced a second competition for the Claude D. Pepper Centers. Awards will be made in FY 1991 if funds are available. At least five high quality projects could be funded, and at an average cost of $1.2 million per year for each Center, an additional $6.0 million in FY 1991 would be required.

PRODUCTIVITY IN WORK AND RETIREMENT

Question. Increasing numbers of able older persons, who now spend 2 to 3 decades of their lives in retirement, constitute an untapped national resource. How is NIA addressing the needs for research on older people's productivity in work and retirement?

Answer. Surprisingly, this untapped resource is widely unrecognized, and research is needed to guide interventions that can improve older people's opportunities for productivity and independence. Many, probably the majority of, older people in fact make significant productive contributions, through volunteer activities and help with their own families' needs. In addition, there are now more opportunities for part-time, post-retirement, paid employment. But such opportunities are far less than desirable. Less than half of men aged 55 and older are continuing in the labor force; it is too soon to predict what the trends will be among the increasing numbers of women in paid jobs.

Yet a decade of NIA-supported research has repeatedly demonstrated two broad principles: active participation in social roles can improve older people's productivity, and their health, intellectual functioning, and independence; but older people's productivity is contingent upon the availability of roles that encourage and reward active participation, and that aid continuing practice of existing skills and learning of new ones. Millions of disengaged older people could become more productive, if these broad scientific principles could be implemented. Toward this goal, NIA's program on Productivity, Work, and Retirement is stimulating specific studies to understand what kinds of roles and environments are needed and how these can improve, or fail to improve, older people's productivity. Two domains are emphasized, the workplace and the household and community.

In the workplace, many older people want and are capable of continuing some form of productive activity, either paid or unpaid. The research program provides a knowledge base on such topics as: older workers' experiences with part-time work, job-sharing, and flexible hours; participation in training programs; success in learning new skills; reduction of workplace injuries and accidents; redesign of jobs and equipment; impact of legislation abolishing mandatory retirement; and factors affecting return to work after retirement, including experience of employers who re-hire retired employees.

In the household and community, many older people, especially those who live alone, want to function independently but have serious difficulty in securing assistance or in performing everyday tasks. The research program provides a knowledge base on such topics as: forms of neighborhood support and social networks; types of housing that reduce loneliness; re-design of automobiles and roads to meet the needs of older drivers; re-design of public transportation; and equipment that frail or disabled older people can use in housekeeping or yard work.

Question. What knowledge base is being laid to guide policy interventions in this area?

Answer. Two types of relevant research are included in the NIA Program on Productivity, Work, and Retirement. First, wide-ranging research projects on how to design interventions to improve productivity in the workplace and the household and community are being considered. These can range in form from descriptive studies to experiments and clinical trials. They are essential for testing hypotheses derived from large-scale cross-sectional or longitudinal studies, of which the Health and Retirement Survey is a prime example. Second, the Health and Retirement Survey will establish a cohort of people and track their health and financial status throughout the stages of pre-and post-retirement.

GERIATRIC PHARMACOLOGY

Question. Several Congressional hearings have highlighted severe health problems and costs associated with inappropriate drug prescribing for older persons. Will NIA's research initiative on pharmacology in geriatric medicine lead to any solutions to this problem?

Answer. A major goal of NIA's Request for Applications, "Pharmacology in Geriatric Medicine," is information to improve drug prescribing for older persons. A study showing the dramatic potential of this type of research recently appeared in the Journal of the American Medical Association: it was found that use of some long-acting tranquilizers were associated with much higher rates of falling leading to hip fractures in older persons than occurred when shorter-acting tranquilizers were used. This information could be translated directly into better drug prescribing. Since the annual cost of hip fractures exceeds $7 billion, a decrease of only 15 percent resulting from better prescribing would save over $1 billion in health costs, not to mention the reductions in disability. I believe that this is only one example of numerous previously unrecognized drug effects which could be revealed by the research solicited in NIA's Request for Applications. This knowledge could significantly improve geriatric care and reduce unnecessary health costs.

Question. In your opinion, what is the scope of the research effort needed to seriously address this issue?

Answer. Two million dollars has been set aside for this initiative in FY 1991. The amount of high quality research that could be funded in this area considerably exceeds this figure. It appears that approximately 100 applications will be received in response to our Request for Applications, and we can reasonably expect that 30 or more will be of the high quality suitable for support. Funding of even a smaller, that is, 25 grants, would require approximately $6 million per year for five years, beginning in FY 1991.

SLEEP DISORDERS RESEARCH

Question. We understand that the National Commission on Sleep Disorders Research has now been established. Given the high prevalence of sleep disorders in the older population, what plans does the NIA have for the development and support of research relevant to sleep problems of older people?

Answer. Disorders of sleep are estimated to afflict over half of the people 65 and older who live at home and about two-thirds of those who live in long-term care facilities. Problems of nighttime sleep and daytime wakefulness disrupt not only the older persons' lives but also those of their families and caregivers. While most sleep disorders are not life-threatening, they have serious impacts upon lessening the quality of life for both the older person directly affected as well as the quality of life of those others in the household of that person. It is now estimated that sleep problems are a major cause of institutionalization into long-term care facilities, as are problems dealing with restricted mobility and incontinence. In one study, insomnia was the strongest predictor of both mortality and nursing home placement for older males.

It is necessary to understand the causes of these disorders and to develop better treatment strategies, including non-pharmacological methods to alleviate these problems associated with later life. The NIA is a major supporter of sleep research at the NIH. In FY 1989, it allocated an estimated $4 million towards the support of sleep research. The NIA is committed to the further stimulation of research on the epidemiology, treatment, and etiologies of these sleep disorders. In FY 1990, the NIA issued a Request for Applications dealing with geriatric pharmacology that also addresses the question of the pharmacological treatments of sleep disorders, such as insomnia in the older population. In addition, the NIA is sponsoring an NIH Consensus Development Conference on the Treatment of Sleep Disorders of Older People in order to reach agreement on determining what changes in sleep are clinically important, how they are best diagnosed and treated, and how the public can establish good sleep practices. The NIA also is planning to support an international symposium on Sleep and Respiration in Aging Adults in FY 1991. Both of these major conferences will provide important new insights and recommendations for new research directions that need to be developed. In addition, these meetings will be very helpful to the National Commission on Sleep Disorders Research in evaluating the state of the art and science in these areas.

TOXINS AND THE AGING NERVOUS SYSTEM

Question. We understand that the aging nervous system may be more vulnerable to toxins. With the increased use of herbicides, pesticides, and other compounds that are neurotoxic, is the older population more at risk? How can we determine the risk?

Answer. One of the most critical issues in the neuroscience of aging concerns the specific mechanisms of selective cell loss in the brain. Neuronal death is especially critical due to the inability of most cells in the adult brain to replicate and replace dead cells. These losses are hallmarks of many of the age-associated disorders of the brain. Aging may increase the susceptibility of the nervous system to toxins and other environmental perturbations. However, few studies have directly addressed this question. Those that have find that one particular brain transmitter system, the dopaminergic system, possesses a clear age-related susceptibility to certain classes of neurotoxins. The question of whether repeated or long-term exposure to low levels of neurotoxins can lead to progressive neurodegenerative processes is likely to be true but is still speculative and needs further research to demonstrate the validity of such an effect.

Pesticides and herbicides contain many known neurotoxins, including organophosphates, carbamates, and paraquat, which have been reported to cause neuropsychiatric disturbances and forms of parkinsonism. The latent neurological effects associated with acute organophosphate pesticide poisonings closely parallel some of the symptoms of Alzheimer's disease and therefore suggest a possible link between exposure to pesticides and this condition. There are regulations concerning the acute exposures to these pesticides. However, three national studies show that 8-10,000 people per year have pesticide poisoning in the United States and about 500,000 worldwide. At the minimum, it is suggested that low-level chronic exposure increases these numbers three-fold. Exact exposure histories for rural farm workers are very difficult to construct retrospectively. In most case-control studies, interviews with patients and controls or review of medical records are two main sources of information on past exposure. Biased recall or faulty memory have frequently been revealed by comparing responses to questions about exposure with documented records of exposure. Furthermore, family members are frequently exposed to pesticides and herbicides brought into the home as residua on clothing and as airborne particles. Thus, direct assessment of exposure risk needs to be done by measurement of body burdens of these chemicals. In addition, well designed epidemiological studies can identify risk factors and exposure histories likely to be related to the neurotoxic potentials of these substances in late life.

Question. What research initiatives is the NIA planning to implement to address this important question?

Answer. To identify areas of research needs and knowledge, the NIA sponsored a workshop on "The Epidemiology of Pesticide Exposure and Cognitive Disorders in Aging Migrant and Seasonal Farmworkers." In FY 1990, the NIA issued a Request for Applications for exploratory center grants on the health and effective functioning of older rural populations. One aspect of this new program is to determine the exposure of older rural residents to particular physicochemical and occupational environments and to determine whether these exposure effects are cumulative and interact with the aging processes. This initiative will supplement existing efforts to stimulate investigator-initiated research proposals addressing questions of specific vulnerabilities of the aging nervous system.

HEARING AND COMMUNICATIVE DISORDERS

Question. In light of the establishment of the new National Institute on Deafness and Other Communication Disorders (NIDCD) and with its mandate to develop programs of research on the older person, is the NIA planning to stop supporting research on hearing and communicative disorders of the aged?

Answer. The NIA is not planning to stop supporting research on hearing and communicative disorders of the older person. Such problems are major contributors to disability and dependency in older persons, and interact with other causes of morbidity with which NIA is concerned. At present, approximately 30 percent of adults aged 65 through 74 and more than 50 percent of those over age 75 exhibit some degree of hearing loss. This percentage may increase in the future as more Americans suffer from noise-induced hearing loss from increased levels of environmental and work-place noise. The prevalence of olfactory loss within the older population may be of similar magnitude. It is unclear whether such problems are normal age-related changes, whether they reflect diseases or iatrogenic causes, such as medications or surgical procedures, that also occur with increased frequency in older populations, or whether environmental factors contribute to these pathologies.

Question. If not, what plans and initiatives does the NIA have specifically directed towards hearing and communicative disorders of the aged?

Answer. The NIA has had an ongoing interest and concern with hearing problems in older people since 1979 when the NIA and National Institute of Neurology, Communicative Disorders and Stroke co-sponsored the first major conference on "Hearing Problems of the Elderly." The NIA has sponsored the National Academy of Science Committee on Hearing, Bioacoustics, and Biomechanics since 1980, and has commissioned this committee to prepare state-of-the-science reports to evaluate the older listener's ability to understand speech and, as well, to identify areas of scientific opportunities for research. As a result of this report, the NIA issued a program announcement soliciting grant applications to examine the nature and extent of age-related differences and changes in older people's hearing and understanding of everyday speech. The NIA also co-sponsored a workshop with the American Academy of Otolaryngology, Head and Neck Surgery to address research questions in the newly evolving subspecialty of Geriatric Otorhinolaryngology. An immediate result of this workshop was the establishment by the NIA of a program of research career awards to support the further training of scientists and clinicians seeking careers in research on hearing and other communication processes related to geriatric otolaryngology. Changes in olfaction and taste occur with age. In about half the population over 65 years of age, odor detection decreases with age, especially to such unpleasant smells as the mercaptans added to natural gas to warn of leaks. The NIA has sponsored a conference on "Nutrition and the Chemical Senses in Aging: Recent Advances and Current Research Needs" in order to plan new directions of research support.

Given the impact of hearing impairments and communicative disorders on older people, the NIA has a major commitment to develop and support research in this area by fostering research on factors that act on the older listener's ability to understand speech, including physiological aging and changes in cognitive ability and development of sensory aides; encouraging research training and development in geriatric otolaryngology; furthering epidemiologic research to further delineate the prevalence of and risk factors for hearing and communication disorders in the aging population; and linking the presence of hearing and communication problems with other neurodegenerative disorders of the aging person, especially the dementias of aging. The NIA expects to work closely with the newly established National Institute on Deafness and Other Communication Disorders in pursuing relevant research areas of common interest.

STATUS OF THE THA CLINICAL TRIAL

Question. Please tell the status of the THA clinical trial. What other promising new drugs or treatments are ready for clinical trials?

Answer. In AD, the most consistent and only neurotransmitter changes that have been strongly correlated with memory loss are the abnormalities in the neurons of the cholinergic system. Tetrahydroaminoacridine (THA), is a drug that inhibits the enzyme that breaks down the neurotransmitter acetylcholine that is produced by the cholinergic neurons. The NIA is supporting a large clinical trial to test the safety and efficacy of THA in the treatment of AD. The trial started in 1988, and after a brief suspension upon the discovery of excess liver toxicity, which has been minimized by use of lower dosages, is continuing after an interim analysis conducted in July, 1989. It is anticipated that the study may be completed within the year, provided that no unexpected problems arise. A closely related compound, HP 029, is under clinical trial by Hoechst-Roussel Pharmaceutical Company using the same study design as in the THA trial.

Currently, there are 16 drugs in various stages of pilot or preliminary study for the treatment of AD. One of these, acetyl-l-carnitine, has proved effective in improving memory in animal studies. The precise mode of action is not known. It has been shown to have some cholinomimetic action, but more importantly it seems to improve mitochondrial metabolic activity. There is an accumulation of evidence that AD may be a reflection of a systemic metabolic effect due to specific defects in mitochondrial enzyme systems. Acetyl-l-carnitine has been shown to stabilize the cognitive functions of AD patients over a 12-month study period.

Another drug under study is nimodipine. Nimodipine is a calcium antagonist, approved for the treatment of strokes, that may prevent membrane changes which interfere with learning. Preliminary evidence from aging rabbits and from people suffering from strokes, indicates that nimodipine may improve memory and possibly restore cognitive function.

Studies in animals indicate that nerve growth factor (NGF) can prevent injury-induced degeneration of cholinergic neurons and improve cognitive functions. NGF may prove to be a valuable treatment alternative for AD. The NIA held a workshop in 1988 on the possible use of NGF in the treatment of AD. Among the conclusions of that workshop were that before human trials are initiated, further preclinical studies in non-human primates are needed to determine toxicity and drug delivery systems, as well as that a reliable source of well-characterized NGF be made available. In light of the progress towards achieving these ends, the NIA is planning to hold another workshop this year to reconsider the status of NGF as a potential treatment for AD.

Huperzine-A is a novel alkaloid compound isolated from the plant Huperzia serrata, the leaves of which have long been used in China as a "memory tea" prescribed by herbalists for failing memory. This compound has now been synthesized. It appears to function as a highly efficacious cholinesterase inhibitor; it decreases the action of acetylcholine by retarding its enzymatic degradation as does THA. Since huperzine-A has been investigated in double-blind trials in China for the treatment of AD and reported to be efficacious, serious consideration should be given to the biological, safety, and behavioral assessment of this agent in this country.

DISADVANTAGED SEGMENTS OF THE OLDER POPULATION

Question. The Congress has repeatedly asked NIA to investigate the special problems and needs of comparatively disadvantaged segments of the older population such as minorities, rural elderly, mentally retarded adults, and most especially the oldest old (those age 85 and over, the fastest growing age category in the U.S.). Please describe the current status and future plans for NIA's research on these populations.

Answer. The NIA supports research targeted to African-American, Asian, Hispanic, and Native American populations, addressing the special problems and needs of these minority groups. Projects funded through the Institute's long-standing initiative on Minority Aging are focused on such topics as older African-Americans with both hypertension and diabetes, and the health behavior and care-seeking of Asian American older people.

Through ongoing epidemiologic studies, the NIA is studying differences between African-Americans and Caucasians in a wide range of topics including life expectancy, effective functioning and healthy aging, dementia, bone density, and vision and hearing. Recently increased competition for limited funds has resulted in a number of very promising studies being unfunded. Nevertheless, future plans include adding minority subjects to ongoing studies of dementia, increased research on ethnic variations in informal, family care for minority elderly, and, depending upon availability of funds, a Request for Applications on specific studies of conditions responsible for physical frailty in older minority populations.

In response to reports indicating the mounting crisis in health-care and other service needs among older rural populations, NIA issued a FY 1990 Request for Applications for exploratory center grants on the health and effective functioning of older rural populations. The topics addressed in this RFA include: the changing socio-demographic and epidemiologic characteristics of the older rural population; the occupational and physiochemical environment; the population aging of rural communities; the availability, utilization, and quality of health-care and other services: and aging rural people as resources. The Institute expects to fund two such exploratory center grants in FY 1990. Depending upon availability of funds in FY 1991, the RFA will be reissued with the goal of establishing two additional centers.

In response to the need for research on the recently growing population of older mentally retarded adults, whose need for long term care is unknown, and whose own adaptive functioning is also unknown, NIA issued a program announcement in FY 1989 on the aging of retarded adults. The topics addressed included demographic and epidemiological research; adaptive functioning; social interactions and family support; intervention strategies; and service and care research. The Institute has begun to fund grants submitted in response to this initiative and hopes to fund further high quality applications in FY 1991.

The rapidly growing 85 plus population represents a group at serious risk for dependency. NIA has issued two program announcements targeted to this group and is stimulating research on risk factors for decline in functional capacity and forecasting life expectancy. While a number of studies have been funded, and some major new databases developed, funds have been inadequate to support many outstanding proposals in this area. Areas identified as needing further support include: improving measurement technologies and cause of death data; developing new longitudinal studies that allow more accurate forecasting; predicting risk factors for functional decline, active life expectancy, and health care usage; linking such data to race and ethnic differences in mortality and disability and to cross-national studies; understanding the dynamic relationship between financial impoverishment and health status; and enhancing existing surveys to improve their capacity for analyzing this population.

MULTINATIONAL STUDY OF DEMENTIAS

Question. We understand that NIA is cooperating with the World Health Organization in initiating a multinational study on dementias. What is the status of this effort?

Answer. The World Health Organization Special Program of Research on Aging (WHO SPRA), in collaboration with the NIA, is developing an epidemiological study of dementia and Alzheimer's disease in five countries, Spain, Malta, Nigeria, Canada, and Chile, with the Coordinating Center located in Florence, Italy. The study is proceeding, and the work is well underway. The Steering Committee recently met in Florence, Italy with colleagues from the Coordinating Center to review revisions to the protocol of work. Over the next six months, the translation of instruments, the construction of the sampling plans, and the standardization of the neurological examination will be completed. Training of the field interviewers and clinical personnel will commence in the fall of 1990. It is anticipated that pilot studies will begin in January 1991. The project is extremely exciting and will provide important new data on the prevalence of AD and other dementias in very different populations and cultures worldwide. It also will have the very important consequence of strengthening the research capability within the collaborating countries.

Question. How successful have you been in developing a sensitive and accurate diagnostic screening instrument?

Answer. The development of screening instruments has been a major foci of the work of the NIA. Many of the instruments presently available have serious flaws and are culturally, educationally, and linguistically biased. The instruments do not provide a fair and accurate assessment of the cognitive function in special population subgroups. Because of the tremendous heterogeneity of the population of older people, it may not be possible to develop a single screening instrument that can be applied to all after appropriate translation. Therefore, the strategy is to systematically compare the available screening instruments in order to understand how they perform one against another. This work is underway in several universities and will ultimately lead to the construction of a smaller number of sensitive and specific screening instruments. It is important that work aimed at understanding the nature of normal cognitive changes with age and the early subtle changes in Alzheimer's disease proceed. Appropriate instruments must be constructed in the light of understanding normal cognition. This is of particular concern for the oldest old where it is unclear what is normal and what is not. Satisfactory instrument development hinges upon an understanding of the disease process against the backdrop of normal aging.

Question. What are the prospects that such an effort would shed light on the question of selective risk factors in the cause of Alzheimer's disease?

Answer. The development of sensitive and specific screening instruments, in and of itself, will not provide information on selective risk factors for AD but, is an absolutely necessary prelude to studies of risk factors. Before it is possible to systematically assess a population for risk factor status, one must know who is and is not cognitively impaired.

Question. We have learned that the disease does not occur in some groups of people. Why can't we exploit this knowledge?

Answer. Some anecdotal but very tantalizing clues regarding the frequency of Alzheimer's disease have been reported in the past year. Reports have been received that suggest the Navaho people in the Southwestern United States, the Cree Indians in Manitoba, Canada, and the Quiche Indians in Guatemala do not appear to experience Alzheimer's disease. In each case, the report was provided based on the clinical experience of a knowledgeable physician. Virtually nothing is known about the dementias in older native Americans. The fact that the three reports arose independently and deal with population groups that are probably genetically related is intriguing. Investigators are now preparing proposals to study the Cree Indians and the Navaho. These are just clues, but certainly very interesting ones, and must be subjected to careful investigation.

It has also been reported that in Nigeria, Alzheimer's disease is absent or at least rare and that upon autopsy the classical plaques and tangles are not apparent. Nigeria is one of the participating sites in the WHO SPRA multi-center study so this lead is being pursued presently.

If significant differences in the occurrence of AD in different national, ethnic or cultural populations can be established, then we can look for and expect to find clues on risk factors and causes for this epidemic disease.

Question. How much will it cost to initiate such multi-national studies?

Answer. Multi-national studies are expensive. In many countries, the actual field and diagnostic work can be undertaken at a cost much less than comparable studies in the United States. However, to launch a multi-national investigation requires a great deal more development and planning work and travel by the participating research workers. It is also imperative that the investigators and their teams meet very frequently with the coordinating center and the other sites during the course of the study so that consistent standards can be maintained. It thus will cost approximately $12.8 million to initiate these multi-national studies.

GENETIC BASIS OF AGING

Question. What progress has been made in identifying the genetic basis of aging?

Answer. Using different approaches and a variety of organisms, several investigators have shown that genetic manipulation can extend life span. Using fruit flies, two investigators have shown that genetic selection for the ability to reproduce late in life is accompanied by an extension of life span of about 30 percent. This life span extension is also accompanied by resistance to starvation.

Another investigator using a small round worm as the experimental organism has shown that mutation can lead to a similar extension of life span. Remarkably it appears that only a single gene has been mutated. This life span extension is accompanied by a reduced production of progeny. Thus, these studies indicate that life span can be manipulated genetically, and suggest that life span may be linked to a variety of reproductive parameters. If it can be assumed that life span is inversely related in some way to the "rate of aging," then it appears that the "rate of aging" may also be genetically manipulated. This remains to be demonstrated.

Another possible example of the genetic basis of aging is found in Werner's syndrome, a human disease characterized by a variety of premature aging characteristics. Although it is a rare disease, Werner's syndrome has now been shown to have a genetic basis. Current research is focussed on discovering the location of the mutated gene in the human genome, and determining the nature of the basic biological defect. Success here could provide dramatic insights into the nature of human aging.

Question. How does this relate to what stops cells from growing, and how does it relate to cancer where growth is out of control?

Answer. One possible cause of aging is the gradual loss of proliferative capacity of cells with increasing age of the organism. Although most of these studies have been carried out on cells grown in culture, experiments where comparisons have been made have usually indicated that these cells mimic the behavior of cells _in vivo_. Several crucial observations have now been made. For instance, senescent cells, which can no longer proliferate, contain a protein which inhibits the growth of young, actively growing cells while tumor, or cancer, cells do not senesce and do not produce this inhibitor. It has been found that at least 4 genes are involved in the control of cell proliferation and at least one of these genes appears to be located on human chromosome 1. Other studies have shown that a protein which acts as a growth suppressor in cancer cells is found in different forms in young and senescent cells and the form found in senescent cells is similar to the form of the protein which suppresses tumor growth, and that the induction of messenger RNA from a cellular oncogene, a gene whose expression leads to cancer, is dramatically reduced in senescent cells.

These studies all suggest that cell proliferation is actively blocked in senescent cells, and that this block may be similar to at least one of the mechanisms employed by the cell to prevent uncontrolled cell proliferation.

MECHANISMS OF AGING

Question. In order to have any hope of identifying intervention strategies to retard the human aging process and to maximize health and well being throughout the life cycle, we must first understand the mechanisms of aging. What progress is being made in this area?

Answer. This question is being approached on many fronts. Clear indications have been obtained that cell proliferation is actively blocked in senescent cells. If aging is partially due to the loss of proliferative capacity of cells, then an understanding of how to prolong or restore proliferative capacity could result in an effective intervention. An increasing percentage of circulating lymphocytes in mice cannot be stimulated to proliferate with increasing age of the mouse which compromises the immune defense system in old mice. This is due at least in part to both reduced growth factor production and a decreased number of growth factor receptors. Several promising interventions are being used to increase the percentage of responsive lymphocytes in old mice. Other research is beginning to pinpoint more exactly where the biochemical defect occurs and this may suggest other interventions which restore immune function.

Macromolecules are large molecules which have complex structure and functions, and whose synthesis requires a large expenditure of energy. Damage to any part of the molecule can lead to partial or total loss of function of the molecule. Thus, cells contain surveillance systems to both prevent damage and to repair it once it occurs. Current evidence indicates that these surveillance systems become compromised in later life leading to an increased number of damaged molecules. Thus, once these surveillance systems, and age-related changes in their activity, are completely understood, interventions can be designed to prevent or reverse these changes.

There are now many well-documented age-related changes in gene expression. Expression of some genes increases with age, and expression of other genes decreases with age. What remains to be determined is why these changes occur, but more importantly which of these changes, if any, are direct causes of aging, rather than a result of aging. Once this information is obtained, interventions can be developed to prevent or delay these age-related changes.

Question. How does the biomarkers initiative relate to this?

Answer. The effects of interventions to delay or prevent age-related changes need to be tested in some more efficient way than looking at the whole life-course of the individual. Many interventions ranging from behavioral changes to ingestion of free-radical scavengers have been proposed for human trials. The biomarkers initiative is a concerted effort to develop a test system to assess the rate at which an organism is aging is less than the life span of the organism. The successful development of a panel of biomarkers of human aging, which we anticipate by 1995, will then allow animal and human intervention trials.

EARLY DETECTION OF ALZHEIMER'S DISEASE

Question. You have told us that one of the stumbling blocks in research and in clinical trials for Alzheimer's disease is detecting the disease very early in its course. Is any progress being made in the development of better instruments and techniques to establish earlier and more accurate diagnosis of this disorder?

Answer. Research to develop an easy and reliable biochemical diagnosis for AD is ongoing, and several promising leads have appeared. The most useful type of diagnostic tool would be a simple blood test, either for serum proteins or biochemical defects in blood cells. Currently, attempts are underway to detect in the serum of AD patients the breakdown products of proteins that accumulate in the brain. Preliminary experiments have detected AD specific proteins in the cerebrospinal fluid of some patients. An exciting possibility being investigated is that blood or skin cells of AD patients may show the same biochemical defects that appear in neurons. Recently, it was reported that accumulations of protein similar to the amyloid protein deposited in AD brain were found in the skin of AD patients. This observation could lead to a skin test for AD. Other metabolic differences have been sought between normal cells and cells from AD patients.

Possible changes have been reported in mitochondrial enzymes and also in the enzymes that regulate cell metabolism by the addition or removal of protein phosphates. The proteolytic enzymes that seem to be centrally involved in AD may also be found to be altered in other cells of the body, but this has not yet been investigated. Identification of one or more defective genes in families with an inherited pattern of AD would lead to straightforward blood tests for AD.

Magnetic resonance imaging (MRI) also shows promise as a diagnostic tool for AD. Patients examined early in the course of the disease showed elevated levels of certain neuronal membrane precursors, which were easily detected by MRI. Prospects for the development of blood, skin, or imaging diagnoses are very good, but considerable research is required. Especially problematic is the slow progression of the disease, which makes any disease-specific changes likely to be subtle. Nevertheless, the exquisite sensitivity of modern biochemical and imaging techniques allows even very small differences to be reliably detected. These differences must only be determined to be truly specific for the disease, and to appear early in its course.

NEW TREATMENTS FOR ALZHEIMER'S DISEASE

Question. What are the prospects for developing new Alzheimer's disease treatments that would produce long lasting effects and help large groups of patients?

Answer. Research efforts stimulated by the NIA are proving to be the basis for the development of new treatments for AD. Currently, as many as 40 existing drugs, compounds, and biologicals have been proposed or suggested as treatments for AD, and there are now 16 pilot or preliminary studies of drugs for AD underway in the United States, some of which are likely to indicate the need for full scale clinical trials. At this time, however, there are no drugs or compounds available that offer the hope of curing or of permanently altering the course of this disease. On the other hand, drugs that can ameliorate the symptoms of the disease, even for a short time, will still be worthwhile since such agents may provide a welcomed relief psychologically and financially to the victims and their families. The current generation of potential treatments focus upon the replacement of transmitter deficits found in AD. New generations of treatments will focus upon nerve growth factors, calcium channel blockers, metabolic enhancers, transport mechanisms for the efficient delivery of drugs, and regulators of gene expression. While effective treatments for some groups of patients may be developed within the next five to 10 years, at the present stage of knowledge, long-lasting cures for large groups of patients will require more time and more research.

TREATMENT STRATEGIES FOR ALZHEIMER'S DISEASE

Question. We understand that the NIA recently sponsored a planning conference on treatment strategies for Alzheimer's disease. Do you have any plans to implement the recommendations of the experts?

Answer. In January of 1990, the NIA sponsored a workshop on "New Strategies for the Treatment of Alzheimer's Disease." The purpose of this meeting was to encourage discussion about new generations of treatment strategies that could be used for Alzheimer's disease (AD). The recommendations of the experts are now being carefully reviewed. They will become the bases for the development of new research initiatives on the treatment of AD. More immediate outcomes have been the development of two more focussed workshops stimulated by the meeting, one on the reassessment of the use of nerve growth factors in the treatment of AD, and the other on the role of the immune system and its modulation in the pathogenesis and treatment of AD.

DEMENTIA IN OLDER JAPANESE-AMERICAN MEN

Question. The Committee understands that the NIA has initiated a research project concerning dementia in older Japanese-American men in collaboration with the National Heart, Lung, and Blood Institute's Honolulu Heart Program. Please describe your progress to date, as well as your plans for this prospective study.

Answer. This project, which has just gotten underway, will be directed by the NIA's Epidemiology, Demography, and Biometry Program in close cooperation with the NHLBI's Epidemiology and Field Studies Program. Data collection and analysis will be supported through contracts and subcontracts with Kuakini Hospital and the University of Hawaii. Both the Veterans Administration and the National Center for Nursing Research have indicated their interest in participating in the research, and both Agencies are considering the assignment of researcher-clinicians to assist in the project.

The cohort to be studied comprises more than 5,000 surviving Japanese-American men who volunteered to participate in a longitudinal study of heart disease and stroke that began in 1963, and who will be 70-90 years of age this year. Over the course of the next four to seven years, we hope to find and diagnose all existing and newly developing cases of Alzheimer's disease and related disorders among the study's participants. Further, we are coordinating our research with Japanese and Taiwanese researchers who will be conducting parallel studies in those nations to insure that our findings will be cross-nationally comparable. This international cooperation is being accomplished through a series of workshops in the U.S. and Japan. Support for the workshops is shared.

When the study is complete, we hope to have defined and compared the age-specific prevalence rates for the major types of dementia; age-specific risk for the development of dementia; frequencies and predictors of different patterns of progression; the influence of factors such as nutrition and religion associated with Western versus traditional Japanese or Taiwanese culture on the development of dementia; and clues or risk factors for the imminent development of dementia, i.e., signs or symptoms that the person is in the very earliest phases of dementia, perhaps even before any cognitive changes are apparent.

INTERNATIONAL AND CROSS-CULTURAL STUDIES

Question. The Committee understands that the NIA has explored opportunities for, and is developing plans to implement a variety of international and cross-cultural epidemiologic studies of dementia and other aging-related concerns. Please update the Committee on the status of the NIA's international activities, the status of the World Health Organization's Special Program on Research on Aging, and the manner in which these activities are coordinated within and by the NIA.

Answer. The various NIA intramural and extramural programs provide limited support for studies involving investigators and unique populations outside the United States. The Institute's Office of International Activities has emphasized international studies on aging by establishing an Institute-wide staff committee for international studies on aging. As one of its initial tasks, the Committee will be asked to provide a coordinated approach to bilateral and multilateral activities such as the October 1989 initiative on "Health of Older Persons," recently submitted through the NIH Fogarty International Center for consideration by the Department of Health and Human Services in connection with the PHS Strategic Plan for International Health.

Examples of other areas that are expected to be advanced for bilateral or multilateral international collaboration include international cross-cultural studies on aging in the Pacific Basin, Latin America, and India; response to congressional report directives with the U.S. Agency for International Development (AID); expansion of the U.S. Bureau of Census International Data Base on Aging; and exploration relating to the U.S. State Department and U.S.S.R. initiative on health of the elderly.

NIA staff continue to contribute to the WHO Program for Special Research on Aging. This Program is located in close proximity to the Institute to enhance WHO access to NIA, U.S., and worldwide scientific expertise, as well as for the provision of NIA in-kind support. Significant progress has been made in securing funding and initiating projects which include Age-Associated Dementias, Determinants of Healthy Aging, Osteoporosis, and Immune Function in the Elderly.

For the Age-Associate Dementias, the protocols have been reviewed and approved, the coordinating center was selected, and most recently the principal investigators from the participating countries of Canada, Chile, Malta, Nigeria, and Spain held their first meeting. The other three areas continue to be developed.

The final draft proposal for the Determinants of Healthy Aging project is currently being prepared for consideration by the WHO steering committee composed of worldwide experts. This cross-national study is designed to identify factors which have a positive influence on the decline of physical, mental, social, and economic function currently associated with aging. By demonstrating which lifestyle factors and activities prevent or delay the onset of disabling conditions, the Determinants of Healthy Aging project can provide new information upon which to base sound decisions for preventive programs that will enhance the independence and productivity of populations as they age.

Among many other activities, NIA has continued to support the International Database on Aging and is planning to develop new editions of the Aging World and Aging in the Third World publications. An initiative that models the impact of health interventions on older populations in a number of countries is also being supported. Following a conference on research on aging in third world countries, consideration is being given to a proposed study in India to investigate the determinants of functional decline in an agrarian community. Efforts are also underway to stimulate research on differences in active life expectancy among the oldest old in a number of industrialized countries. Special efforts are being made to develop research on the aged in the Eastern Block and Soviet Societies.

HEALTH AND RETIREMENT SURVEY FUNDING

Question. What resources are required to adequately carry out the Health and Retirement Survey that Congress has urged you to undertake?

Answer. In FY 1990 the Congress appropriated $500,000 for the design and planning of this study. The cost to continue this survey in subsequent years is estimated at $2 million; therefore, an additional $1.5 million will be needed in FY 1991.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

OLDEST OLD

Question. Dr. Williams, the estimated growth in the population of persons 85 years of age and older is projected to rise dramatically by the middle of the next century. Has the Institute examined the implications this will have on our nation's health care delivery system, the cost and the changes that will be necessary to meet these increased needs?

Answer. The population over age 85, the oldest old, is regarded by the Census Bureau to be the fastest growing age group in the nation. However, a number of researchers have developed forecasts that dramatically exceed the Census Bureau's high range projections for the middle of next century. One of these projections, using a modelling or simulation method, has indeed forecast that healthier life styles, such as reducing smoking, hypertension, and cholesterol, could plausibly result in some 40-60 million people over age 85 in year 2050 or 2060. It is important to remember that this is an extreme projection and is not necessarily the most likely.

The implications for health care costs are astronomical, since the 85 plus age group have the highest morbidity burden of all groups and also are the greatest consumers of health care and federal benefits for the aged, in part because they also have the highest level of impoverishment. The increased costs due to population changes alone will be of a very high order of magnitude, but could be lessened or compounded depending upon whether or not increased life expectancy is accompanied by better or worse health.

The National Institute on Aging has in place an initiative on the Oldest Old that includes a focus on developing better methods to forecast both life and disability expectancies. The Institute has also begun to invest in the databases, such as the National Long Term Care Survey, needed for making better projections. Contingent upon the availability of funds, the Institute is now ready to include in the Oldest Old initiative the development of microsimulation models. These models will help identify the implications of the dramatic growth of this population for the country's health system and costs, and will also evaluate the impact of alternative changes.

ATTRACTING YOUNG INVESTIGATORS

Question. What is the NIA doing to attract young investigators into the field of aging research?

Answer: NIA recognizes the importance of attracting young investigators into the field of aging research. In addition to the regular training mechanisms available for scientist and clinical investigators, special initiatives have been announced to provide opportunities for new clinical investigators to be trained. Further, the NIA has developed innovative approaches for attracting investigators by instituting complementary training grants that allow institutions to add aging research training components to existing non-aging training grants. For example, training programs in demography, cardiovascular science, and neurology have added trainee positions that have attracted several high quality pre- and post-doctoral scientists to the field of aging. While this approach has been effective and economical, it is now time to take advantage of the growing interest in aging research stimulated by these complementary training grants and to establish training programs dedicated solely to research on aging at these institutions and other institutions. NIA also supports a special initiative to fund minority new investigators and trainees by supplemental funding to ongoing research project grants and training grants.

TRAINING GRANTS

Question. How many training grants do you anticipate supporting in 1991? In your professional judgement, is this sufficient or should we be supporting more?

Answer. In FY 1991, NIA expects to fund 92 training grants which will support 385 full time training positions, as well as 91 career development awards. The need to attract young investigators into the field of aging research will require the support of considerably more training and career development opportunities. In my professional judgement, NIA should fund at least 106 training grants which will support 638 full time training positions and 104 career development awards.

FUNDING FEWER NEW AND COMPETING GRANTS

Question. Dr. Williams, I note that the NIA budget for FY 1991 estimates funding 41 fewer new and competing grants then received funding in FY 1989. In light of the challenges that will be facing our nation with the growth in the aging population, is this a wise course of action?

Answer. The field of aging research, as a newly emerging area of science, relies very heavily on recruiting new investigators by attracting scientists trained in other areas of biological science, which is critical to maintaining the momentum we have generated over the last ten years. Within the funds available, we will make every effort to maintain our commitment to this area.

Question. Will this have a chilling effect on researchers entering the field of aging research?

Answer. There is no question that this will have a chilling effect on aging research both next year and in the near future. Our staff, however, will continue their efforts to work with the scientific community to modify the effects this may have.

FUNDING RATES

Question. What percentage of approved grants do you anticipate funding in FY 1991? How does this compare with FY 1989 and FY 1990?

Answer. NIA anticipates funding 17 percent of approved competing research project grant applications in FY 1991. This compares to 19.4 percent in FY 1990 and 25.6 percent in FY 1989.

DOWNWARD NEGOTIATIONS

Question. What do you anticipate will be the rate of downward negotiation, both for research project grants and center grants?

Answer. The FY 1991 downward negotiation rates for noncompeting and competing research project grants will be 10.5 percent and 10.4 percent, respectively. The FY 1990 rates are 13.0 percent and 15.4 percent, respectively, and in FY 1989, they were 12.5 percent for noncompeting and 10.0 percent for competing.

We anticipate a 21.4 percent downward negotiation rate in our research centers program in FY 1991. In FY 1990, the rate is expected to be 17.8 percent, while in FY 1989, research centers were funded at full cost.

HEAD INJURY

Senator **Harkin**. Dr. Goldstein, last year you told the committee of conclusions reached by the interagency task force on head injury and requested an additional $15 million. Unfortunately, we were unable to fund an increase for head injury research at your Institute, although we were able to provide $15 million in the Department of Education, Rehabilitation Services and Handicapped Research Program, for the establishment of four regional comprehensive head injury research centers.

You understand that these centers will do research in patient treatment and maintenance regimens. Do you feel that the funding of these regional centers will advance the concerns that you expressed regarding head injury?

Dr. **Goldstein**. Yes, sir; I do. The head injury task force addressed two separate issues, although they are related. One is patient services. There is a very large number of people who are seriously damaged due to head injury. They need treatment and they need it very badly.

The funds made available to the Department of Education through its Rehabilitation Services Administration will assist in doing just that.

On the other hand, somewhat like the polio days, one can treat people indefinitely with permanent neurological damage. The real answer was to eliminate the need of respirators.

The proposal for establishing head injury research centers was the counterpart, namely the opportunity, to develop methods of intervention which, when applied at the time of injury, would assist victims so they would not need rehabilitation therapy or at least would not need as much. It was that program which was not funded.

DECADE OF THE BRAIN

Senator **Harkin**. Let me ask you, this is the "Decade of the Brain."

Dr. **Goldstein**. Yes, sir.

Senator **Harkin**. But you know, I have read all about this and perhaps it is just something that I have not come across, but do we have defined goals for the end of this decade? What are the goals of the "Decade of the Brain?"

Dr. **Goldstein**. Thank you for that question. I expect to have in your hands by June 1, an eight page "Decade of the Brain Implementation Plan" which will specify its goals and implementation methods, particularly those which can be achieved within 3 years.

The National Advisory Council of the NINDS has sent a memorandum nationwide, not only to doctors and scientists but to the health groups, the public, people with multiple sclerosis, people with head injury, asking them to help us define the needs.

Then on April 17, 1990, there will be a national consensus meeting in which the public and scientists will sit down together and discuss what are the realistic goals for the "Decade of the Brain" and particularly its first year.

The resulting plan will be reviewed by the NINDS Council in May and sent forward as the Council's document on the "Decade of the Brain," and it will be in your hands by June 1.

NEUROGENETICS RESEARCH

Senator HARKIN. Again, tieing into the human genome project, you mentioned that 25 percent of—how did you say that?

Dr. GOLDSTEIN. Twenty-five percent of all human genetic disorders involve the brain and nervous system.

Senator HARKIN. Right. What assistance do you hope to have from the human genome project with regard to solving the mystery of these genetic disorders?

Dr. GOLDSTEIN. It will be the underpinning of our neurogenetics research program. Let me use the search for the Huntington's disease gene as an example. We have been searching for the Huntington's disease gene for 7 years. We know which chromosome it is on, but we have not been able to localize the specific site. It is there somewhere, but as of yet, we have not been successful.

If the human genome project is successful, and I assume that it will be, it will have, in many ways, provided a library of what sequences up and down that chromosome so that investigators interested in a specific disease will be able to more easily identify an abnormal sequence.

At the moment we have to do the looking ourselves without the broad base. The human genome project is an underpinning for our future research.

Senator HARKIN. Dr. Raub, I still want to know if it is possible to collapse the timeframe on this project. I heard it was going to take 10 to 15 years.

I am not asking for a response now, but if you could provide me with more information on that. I do not want to do something that is not scientifically feasible or is not in keeping with scientific progression, but if we can leapfrog or move some things, I would like to know that. I would like to know if this can be pushed in any way. We might be able to obtain more funds if we can push this faster than the projected 10 to 15 years.

I would like to know. But if there is not a way to speed up the progress, then I am willing to accept that. For some reason there is something inside me telling me and I am not convinced that it cannot be pushed.

Dr. Goldstein, I understand you have been required to reduce the number of PET centers—positron emission tomography.

Dr. GOLDSTEIN. Very good, sir.

PET CENTERS

Senator HARKIN. Please tell us how many centers you have defunded and what the impact of this has been?

Dr. GOLDSTEIN. We have taken two administrative steps. One, by the end of fiscal year 1989, we had discontinued support for two pet centers. They are now closed if I may use that term.

Second, and of equal consequence, we have had to cut the research funding of the ongoing ones, some of them up to 50 percent of the approved amount.

What is its impact? Positron emission tomography has now entered the phase where it is becoming, I hate to use the term, significant. As an example, in drug addiction, where do the drugs work in the brain? How do they affect brain metabolism? Metabolically, what does the term addiction mean?

It is one thing to say that the patient is on drugs and is high, but what does that mean in biologic terms? Where specifically in the brain are those drugs working, and how do they work on that part of the brain?

Is it an increase in certain biochemical activity? Is it a decrease in certain biochemical activity? Positron emission tomography provides us with the opportunity to investigate those questions. We have had to discontinue all of these projects. What more can I say?

Within the budget available to us, we had to make some cuts in order to maintain meaningful research balance among programs. Some projects have been cut 50 percent below their recommended level of support.

Senator HARKIN. Thank you very much, Dr. Goldstein. For you and for the rest, I will have additional questions for the record.

Dr. GOLDSTEIN. Thank you, sir.

ADEQUATE SPACE

Senator HARKIN. Dr. Snow, again, I want to welcome you as the new director, first director of our National Institute on Deafness and Other Communication Disorders.

I want to work with you to make sure the Institute is up and running at full speed. In that regard, I wrote Dr. Raub in November to request his assistance in making sure that you had all the necessary facilities and a fair share of existing space. I guess it is in building 49.

What is the current status of the space that has been allocated to the Deafness Institute and do you have adequate space to get it up and running?

Dr. SNOW. Thank you very much for that question. Space is a problem to our Institute, but it appears there is a light at the end of the tunnel. We are in the final stages of discussing the assignment of the D wing of the fifth floor of the clinical center for our intramural clinical research program.

We are hoping to develop a portion of our intramural research program in rental space in the Gillette Building, and we are hoping to accommodate the administration of our extramural program in rented space in the Executive Plaza Building.

Ultimately, we hope to consolidate the Office of the Director of the NIDCD in the C wing of building 31.

MULTIDISCIPLINARY CENTERS

Senator HARKIN. Dr. Snow, we asked for the establishment of five multidisciplinary centers and we provided funding for these centers for this year, fiscal year 1990.

Dr. SNOW. Yes, sir.

Senator HARKIN. I understand that as of late January, the Institute had received 42 requests for application information. Your application period will be opened until March 22 so you probably will receive even more, I assume.

When did you expect to make your awards for these centers and will you be able to fund all five in this fiscal year?

Dr. SNOW. We hope to make the awards in September. It will be done in this fiscal year. We are hoping to fund three or four centers with the funds that are available in fiscal year 1990.

As you may know, these centers are of great importance because they support both basic and clinical research, research training, continuing professional education, and outreach to the affected and the public, and we think that these will be a great national resource.

Senator HARKIN. What could you do if you had more money for centers?

Dr. SNOW. We could establish more centers. I believe that we could have more than five excellent centers.

OTOLARYNGOLOGIST-RESEARCHERS

Senator HARKIN. Last year the committee discussed the fact that there are only 50 Ph.D. otolaryngologist researchers in the entire country.

Dr. Moskowitz agreed with us that this was an inadequate number to begin an aggressive research program. What is your estimate, Dr. Snow, on how many fully trained researchers would be required to mount an adequate research program in the areas covered by the Deafness Institute? Is the training budget request adequate to meet this level?

Dr. SNOW. If you look at all of the investigators whose work is supported by the National Institute on Deafness and Other Communication Disorders, the number is somewhere around 525. Only 50 of those are otolaryngologists and so it is important that the number of otolaryngologists be increased. We also want to increase the number of other investigators, particularly by attracting molecular biologists to these areas of study.

We must emphasize research training in this Institute, perhaps to a greater degree than is generally true, and we have convened a panel of experts. They met in Boston in July of last year, and they recommended a number of important training initiatives.

Some of these have been implemented. Some are in the planning stage. They include greater research training at the predoctoral and postdoctoral level, the initiation of the Physician Scientist Award, and the Mentor Award which is a very innovative approach to research training, wherein an established, distinguished scientist whose work is supported by the NIDCD can apply for additional support for a traineeship to be carried out in conjunction with their supported research.

We are also emphasizing the training of minority individuals and communicatively impaired individuals in our training program. If more money were available for training, more individuals could be trained. We cannot fund now all of the individuals wishing to receive training.

Senator HARKIN. What percent would you be able to fund?

Dr. SNOW. I believe we can fund approximately 90 percent.

EPIDEMIOLOGY

Senator **Harkin**. You say you have little or no research in epidemiology. How can this be improved?

Dr. **Snow**. This is an area that has not attracted the attention of the epidemiologists in the past and yet we very much need this information. We want to carry out the legislative mandate to develop sound epidemiologic information in hearing, balance, smell, taste, voice, speech and language, and we have planned a conference on epidemiology and population-based studies to be held later on this year.

This will serve as a framework for developing epidemiologic studies. As a first step we are going to issue a request for proposals on the epidemiology of specific language impairments, and this will occur in this fiscal year, and will cost around $300,000 per year over a 5-year period.

This disorder is a major factor in learning disabilities, what is known of as dyslexia and in difficulties of learning to write.

CLEARINGHOUSE

Senator **Harkin**. Last, what can you tell us about the progress to establish a clearinghouse that we had provided funding for?

Dr. **Snow**. We will be issuing a request for proposals in the very near future. This has to be done in a careful fashion, so that we do not duplicate existing resources.

Part of the guidelines for the clearinghouse is that the contractor utilize existing sources and not duplicate existing efforts.

Senator **Harkin**. Dr. Snow, thank you very much. I will have some additional questions for the record.

Dr. **Snow**. Thank you very much, sir.

LABOR SHORTAGES IN BIOTECHNOLOGY

Senator **Harkin**. Dr. Kirschstein, a survey conducted last year by the National Academy of Sciences showed that many of the Nation's biotechnology firms currently have problems hiring scientists and over one-third report having labor shortages. Is this accurate?

If so, why is it happening and what are the consequences of this?

Dr. **Kirschstein**. I think it is an accurate survey result, and I think the reason it is happening is that, as my colleagues and I have told you throughout the day, there is a serious shortage of well-trained individuals, particularly individuals trained in the basic biomedical sciences of molecular biology, chemical engineering, biophysics, and cell biology. These are the disciplines required by the biotechnology industry.

The problem is that if well-trained individuals in these disciplines are not available, the biotechnology industry will flounder and this, in turn, could cause problems for the economic well-being of the United States.

We are in serious competition throughout the world for leadership in what we in this country have always done best, which is to apply basic research to the commercialization of important products, not only for medicine, but also for the agricultural aspects of our country's economy and that of many other countries.

The biotechnology relies heavily on the work of well-trained individuals. Without them, I believe the industry will be in serious trouble.

BIOTECHNOLOGY TRAINING PROGRAM

Senator HARKIN. This committee had set a goal of 1,500 biotechnology research trainees by 1993. Are we on the right track?

Dr. KIRSCHSTEIN. Yes; I think you are on the right track with the ultimate goal, but are you asking about whether we are on the right track now?

Senator HARKIN. Meeting the goal?

Dr. KIRSCHSTEIN. In that respect, we are vey much off track. The goal, as you said, is to have 1,500 trainees by the fifth year, which would be fiscal year 1993. The initial 5-year plan called for 500 for the second year, which was fiscal year 1990, and we are currently supporting 190 trainees.

Senator HARKIN. One hundred and how many?

Dr. KIRSCHSTEIN. We had hoped to have 500 by the second year, which is the current fiscal year, and we are only going to support 190.

Senator HARKIN. That's amazing. Well, why does not your budget request reflect an increase of 250 over the present 190?

Dr. KIRSCHSTEIN. Mr. Chairman, within the constraints of all the demands of the budget, this was the best we could do.

Senator HARKIN. I am just wondering if we should not take another look at that? Your increase is in general proportion, 4.7 percent. If this is an area of high priority perhaps something should give way to this so that we could have that number back up again.

Dr. KIRSCHSTEIN. Mr. Chairman, when the committee of experts looked at this issue and made a report 2 years ago, or really closer to 3 years at this point, it was felt that, not only were there training needs for individuals who could work specifically on biotechnologically applied activities, but there also was a really critical need for well-trained scientists in multidisciplinary basic areas as well.

And those individuals are in short supply also. Indeed, programs for research training throughout NIH and, particularly in the National Institute of General Medical Sciences, have not kept pace with needs as one might anticipate.

The National Academy of Sciences which has been doing studies on manpower needs for biomedical research over the years in its latest report, has estimated a shortfall in the traditional research training programs in 1991 somewhere in the order of 800 trainees.

NEI HEALTH EDUCATION PROGRAM

Senator HARKIN. We may have to take another look at that. Well, I wanted to talk a little bit about the Human Genome Center. We will get that in writing.

I want to move to Dr. Kupfer here. Dr. Kupfer, the committee urged your Institute to push for full implementation for a national eye health education program.

I understand that 50 percent of diabetic patients are not receiving available treatment in order to maintain good vision. Glaucoma is another chronic situation which can be effectively managed if people are aware of the need to seek help. What is the status of your health education program?

Dr. **Kupfer**. Sir, last March we held a national planning conference to which there were more than 65 participants representing a diverse group of 35 professional, voluntary, and government organizations, individuals involved in eye health care, as well as pharmaceutical companies.

As a result of this 2 day meeting, a number of recommendations were put forth which we have been implementing since then. Just this January we constituted a planning committee that has given approval to additional actions on these recommendations which we have already begun implementation.

One of the most important things that we are going to do this fiscal year is conduct research to determine the knowledge, attitudes, and practices of the public with reference to their understanding of glaucoma and diabetic retinopathy. This effort will help establish a base upon which additional aspects of the program can be developed.

We are also in the process of implementing a pilot study, to start a national toll free telephone information service to be able to respond to questions from the American public.

We are also planning some research and demonstration projects to determine the most effective ways to educate patients with diabetes. This effort will help to ensure that they understand the risk factors for the development of blindness and how they can seek help to reduce this risk of blindness by more than 50 percent.

We also want to educate those at high risk for glaucoma: in particular, blacks over the age of 50, and in general, persons over the age of 65, to make them more aware of glaucoma and to seek comprehensive eye examinations.

We are moving toward establishing a national eye health program which will be based upon sound research information that can be effectively conveyed to people who either have or are at risk to these diseases, and their health-care providers, and then properly evaluating the results of these activities.

NEW DRUGS FOR ALZHEIMER'S DISEASE

Senator **Harkin**. I have some other questions I wanted to ask you about why your percentage of funding is so high in grants, 40 percent, but we will get that in writing.

Dr. Williams, just one thing for you. We learned that there are 12 to 16 new drugs to treat Alzheimer's disease being tested in Europe, but we only have one clinical trial in this country underway. Why is that?

Dr. **Williams**. There are several reasons for this. One is that we are proceeding carefully with the trial of tetrahydroaminoacridine, or THA, which is similar to a number of drugs that are being tested in other places. We fully expect an answer on the efficacy and safety of THA before this year is out.

We do have other drugs that we would propose to test, depending on the availability of funds. The drug acety-d-carnitine shows promise and there are several derivatives of other drugs that have promise.

As I mentioned before, nerve growth factor is a definite promising medication preparation that we hope to test within the next year or two. The development of further clinical tests will depend upon the availability of funds.

Senator **Harkin**. We have 115 drugs for AIDS now in clinical trials and you are saying next year, maybe only what, another——

Dr. **Williams**. We anticipate that we could begin one or two additional clinical trials next year.

ROLE OF INFECTIOUS AGENT IN ALZHEIMER'S

Senator **Harkin**. I am also intrigued by your statement that there might be an infectious agent or something like that causing Alzheimer's disease.

Dr. **Williams**. There has been one very provocative study from Yale indicating that an agent could be extracted from the white blood cells of families with a genetic form of Alzheimer's disease and produce a lesion in the brains of hamsters, this could then be transmitted to a second generation of hamsters.

It appeared to be a true transmissible agent, but only one study has documented this with Alzheimer's disease. This year we will fund two other studies which will repeat this work and determine, we hope, the validity of this observation.

If the observation is repeated, it is an extremely important finding.

Senator **Harkin**. Thank you all very much. We will recess for about 15 minutes and then we will pick up with panel 5.

[A brief recess was taken.]

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

STATEMENT OF DR. LAWRENCE E. SHULMAN, DIRECTOR

SUMMARY STATEMENT

Senator **HARKIN**. The subcommittee will resume its sitting. Our last panel is here and we will do the same thing, we will just go down the line and have questions after you all testify. Again, as before, all of your statements will be made a part of the record in their entirety, and if you would summarize them I would appreciate it.

First is Dr. Shulman, from the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Your Institute now is 4 years old?

Dr. **SHULMAN**. Yes, sir.

Senator **HARKIN**. And up and running. We look forward to hearing your statement. Your request for next year is $176.08 million, that is a 4.23-percent increase.

Dr. Shulman, again, welcome and please proceed.

Dr. **SHULMAN**. Mr. Chairman, once again, it is a great privilege to appear before you on behalf of the National Institute of Arthritis and Musculoskeletal and Skin Diseases. I repeat the name again only to emphasize that we have a very large research mandate.

Within those three names are five different fields of medicine, and each of them has a broad and deep research agenda. For example, there are over 100 different types of arthritis, as you know, and the numbers of skin diseases are even larger than that.

I will briefly share with you some of the highlights this year. We have had a very good year in terms of research accomplishments.

Let us start with Lyme disease. It is still increasing, as you know, and is the most frequent vector-borne disease in the United States. We discussed last year the problem of diagnosis. It is underdiagnosed early, overdiagnosed late.

We needed some new tests and we have now developed such new tests. One of the researchers we support has developed a test for detecting Lyme disease in the urine. Using the polymerase chain reaction, as Dr. Fauci mentioned this morning, intramural scientists at the Allergy Institute have developed an excellent new test to pick up very small numbers of bacteria in the tissues, in the joints, for example. Also we are able to grow the organism from the blood of patients with this disease. Therefore, we have made some progress in this arena.

We do not know what the bug does in the body. Here, we have an example of even when knowing what the causative agent is, we do not know how it produces the disease, especially its late manifestations.

For that reason, we and the Allergy Institute issued a request for applications for research on the causes of Lyme disease. We received 45 research applications from that announcement, and as a result we will be able to support some excellent research as to how this disease comes about.

Now let us now turn briefly to arthritis research. We have had some encouraging developments. As you know, sharing your interest, we have been working hard on the whole question of finding infectious causes of arthritis.

We issued a program announcement for more research, and we have done well. You asked us to support $5 million this year on infectious and other causes of rheumatic diseases. In research on infection alone, we will be expending more than $5 million in 1990. In 1989 we expended $4.9 million, supporting 31 grants, three on mycoplasma which is an area of special interest to some.

We made progress on the treatment side. Methotrexate has proven to be a very effective treatment for rheumatoid arthritis and has just this year been approved by the FDA. We have other effective agents for other types of arthritis as well.

We have much going on in osteoporosis. As you know, our Institute is the lead agency for osteoporosis research. We have new findings on mechanisms of bone loss and we have made progress on how to measure bone density, new techniques have been developed.

We have other studies on fluoride, which will be published shortly, of a long-term study indicating that there is a difference between what you measure in terms of bone mass and the quality of the bone. It indicates that we need even better measurements than the ones we have today. Moreover, we have developed new data with respect to both preventive strategies and treatment strategies for osteoporosis.

I could go on, but will not do so. We have new developments in research on lupus and on osteoarthritis, and on the severe blistering diseases of epidermolysis bullosa and pemphigus that are both serious skin diseases.

I would like to close with just two points. The first, and the major one, is that we have appreciated your interest in our intramural research program. We started off with a rather modest intramural program, and you advised us, and in fact ordered us, to spend a part of the increase you gave us this past year in developing further the intramural research program.

We have done that. The NIH has given us some additional space, and we are very grateful for that, to develop the intramural program. We have recruited a new laboratory for skin biology with Dr. Peter Steinert as its director.

We have had very gratifying developments with the orthopedic research program. Also we plan to initiate a laboratory of structural biology, which will be a great resource for all at the NIH.

We expect to have additional space coming down the pike, as promised, and we have plans for further development of the intramural program.

PREPARED STATEMENT

Last, we have developed the organization for developing our national plan. I have awaited, as you know, senior staff to come and join with me for that. We were able to recruit Dr. Michael Lockshin, a professor of internal medicine from Cornell, to join our Institute as the head of extramural programs. He and I, along with a deputy director, also to be recruited and appointed, will be leading that effort which will take some 2½ years, and we have to spread our resources over those 2½ years to support and accomplish this special, comprehensive mission.

Thank you very much.

[The statement follows:]

STATEMENT OF DR. LAWRENCE E. SHULMAN

It is my great privilege to share with you some of the accomplishments, latest research advances, and opportunities for research by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) this past year, and to present some of our plans for the future. The mission of the Institute embraces a wide variety of disorders; most of which are long-term and disabling. These diseases affect millions of Americans, exacting an enormous toll in human suffering and placing an immense economic and social burden on the Nation.

One of the most rapidly growing problems is Lyme disease, which affects many parts of the body and is caused by screw-shaped bacteria that are transmitted by ticks. Some 5,000 new cases were reported last year; and it is increasing. Because its symptoms closely resemble those of other illnesses, early diagnosis of Lyme disease is often difficult. We are hopeful that a urine test, developed by our researchers, that uses highly specific antibodies will prove to be a better diagnostic instrument than the blood tests now available. Another promising lead has emerged from a US-USSR study, showing the existence of Lyme disease in different regions of the Soviet Union, and apparent differences in the strains of the causative bacterium in the different regions. This could explain regional differences in the expression of Lyme disease.

To encourage more research on Lyme disease, the Institute has issued, jointly with the National Institute of Allergy and Infectious Diseases, a request for applications pertaining to its pathogenesis. The NIAMS has also issued a program announcement focusing on clinical and epidemiological research on Lyme disease. The responses to these two initiatives have been highly encouraging.

Rheumatoid arthritis is of major concern to our Institute and to the 2.1 million adults in the United States who suffer from it. Good news with regard to the treatment of this potentially crippling disease was establishing the efficacy of methotrexate. Definitive therapeutic trials have reconfirmed its safety, and the Food and Drug Administration has recently approved its use for treating arthritis.

This year, the NIAMS is initiating a multicentered clinical trial of minocycline (a form of tetracycline) for the treatment of rheumatoid arthritis. It is based on the recent demonstration that minocycline inhibits the activity of collagenase--an enzyme that breaks down cartilage and bone in the joint. If the drug proves beneficial, investigators might then develop and evaluate a new form of tetracycline that retains the collagenase-inhibiting properties of minocycline, but not its antibiotic properties.

The Institute is pleased by the response that its program announcement, requesting research proposals on infectious causes of rheumatoid arthritis, has evoked. This year, a new approach has emerged for the study of this important area. For the first time, researchers have succeeded in genetically manipulating mice to carry a specific genetic trait that is closely associated with spinal arthritis in man. The ability of infectious agents to induce arthritis in these mice is being evaluated.

Numerous Americans, largely young women, suffer from systemic lupus erythematosus (lupus), an inflammatory, immune-mediated disease that causes distinctive rashes, arthritis, and life-threatening kidney damage. Lupus is found much more frequently in women than in men (9 to 1) and affects more blacks than whites (3 to 1). Recent research indicates that different autoantibodies, antibodies that react against the body's own tissues, are closely related to specific clinical features of lupus. From sophisticated immunogenetic investigations, we are learning that immunologic abnormalities are frequently found in female relatives of lupus patients, thus providing valuable information about how the disease is genetically linked. Important questions remain regarding the epidemiology of lupus and the undiscovered factors that trigger the immunological defects. The Institute is also encouraging enhanced research on other major rheumatic diseases: arthritis of children in its many forms; Sjogren's syndrome;

systemic sclerosis and other forms of scleroderma; and the spondyloarthropathies (arthritis of the spine).

Twenty-four million Americans are estimated to have osteoporosis, the leading cause of bone fractures, both in postmenopausal women and in the elderly in general. A major, long-term clinical trial supported by the NIAMS has shown that fluoride therapy to reduce the incidence of fractures in older women is not effective. Recent research, however, has indicated that physically active young women have more dense bone in the spine than do young women who are physically inactive; and this is encouraging in terms of developing a preventive strategy.

The NIAMS is sponsoring a scientific workshop on osteoporosis in February 1990 to enhance communication among investigators and speed research progress. The Institute is also collaborating with the World Health Organization and the National Institute on Aging to conduct important epidemiological studies on osteoporosis.

Osteoarthritis is the most common form of arthritis, affecting both the middle-aged and the elderly. It is thought to be caused by degenerative changes in the cartilage of joints. Recently, investigators employed a new microscopic computerized X-ray technique to detect the sequence of events leading to osteoarthritis; they found that the earliest changes occur in the bone that lies just beneath the cartilage. In other research, investigators are studying the interaction between porous-coated joint replacements and the surrounding bone tissue to enhance both the stability and longevity of joint replacements. In addition, a recent workshop discussed biologic restoration of joint surfaces using graft materials.

Paget's disease of bone is another chronic disease characterized by excessive resorption of bone and formation of new bone. This abnormal turnover results in bone that is dense but fragile, often leading to striking bone deformities, such as an enlarged skull or bowing of the legs. Research on bone cells in tissue culture has shown that as bone is resorbed, regulatory growth factors are released. These growth factors may prove to be important in developing new strategies for treatment.

Over 100 different conditions are included among the heritable connective tissue disorders. Their clinical impact ranges from mild to devastating disability, and even to death. Among them are osteogenesis imperfecta, Ehlers-Danlos syndrome, Marfan's syndrome, and epidermolysis bullosa. Modern molecular biology now makes it possible to gain better insights into how basic genetic defects lead to the specific clinical symptoms of each disease. The Institute has convened a major scientific workshop to be held in April 1990 to bring together leaders in this field and set future research priorities.

Reducing risk of injury is important to millions of Americans who participate in exercise programs and sports. The results of a recent workshop on the inflammation that is generated by sports-induced tissue injury will be published shortly. A program announcement based on the recommendations from this workshop will be issued to stimulate research in the fields of musculoskeletal fitness and sports medicine.

The contraction and relaxation of muscle is modulated through release and sequestration of calcium by channels that function within muscle cells. By exploiting recent advances in genetics and genetic engineering, investigators are learning more about the relationship between the structure of these channels and their function. The Institute has planned a workshop that will focus on the structure and function of the principal molecules of muscle cells.

We continue to make significant progress in addressing the many skin diseases that afflict Americans. Among these is epidermolysis bullosa (EB), a group of devastating blistering diseases. We are especially encouraged by the discovery of an inbred strain of alpine sheep that manifests the characteristics of one of the most severe forms of the disease. Use of this animal model will greatly facilitate research, including drug intervention studies.

In a FDA-sponsored clinical trial, phenytoin, an anticonvulsant, that had been reported to be promising for the treatment of EB, was shown not to be effective. We anticipate testing other candidate drugs on the patient population that is now being recruited by our National Epidermolysis Bullosa Registry. The registry will also identify separate populations that can be used to investigate the various forms of EB and delineate the causal mechanisms of these diseases more precisely.

Alopecia, which results in loss of hair, can be very debilitating psychologically. We have recently convened a scientific advisory group who recommended further studies on the basic biology of hair and its diseases. Recent improvements in organ culture techniques and the development of new animal systems to test drugs to combat hair loss make research in this area particularly promising.

The NIH Consensus Development Conference on Sunlight, Ultraviolet Radiation, and the Skin that we co-sponsored last May was a great success. Many recommendations related to human exposure to natural and artificial ultraviolet (UV) light emerged from the conference, as well as recommendations for further research, including immune dysfunction of skin by such exposure, intrinsic aging versus photoaging of skin, and the potential role of retinoids in reversing the damage.

A scientific workshop on psoriasis recommended additional research on the molecular, immunologic, and pharmacologic aspects of this prevalent skin disease, and we are pursuing these approaches. Another area of research that seems to be particularly timely concerns wound healing. The recent development of "second skin" dressings and animal models with impaired wound healing, for example in the diabetic rat, will facilitate further progress in that area.

I am delighted to report to you the significant strides we have made in our Intramural Program. Effective January 1, 1990, we inaugurated the Laboratory of Skin Biology, whose primary mission is the conduct of basic research on skin. Moreover, our Orthopaedic Research Laboratory has been particularly productive this year and has rapidly become an integral part of the Institute's Intramural Program. Additional space has been made available to the Institute for the further development of the Intramural Research Program.

In an advance that may usher in a new era in the treatment of immune-mediated diseases, NIAMS intramural scientists have determined the complete structure of a key protein in humans involved in triggering allergic reactions. They are now focusing their research efforts on a search for drugs that will prevent allergy attacks. Other breakthrough research conducted in the Institute's Intramural Program demonstrated a defect in the neuroendocrine response to inflammation in an animal model of persistent arthritis. This could shed light on causal factors in rheumatoid arthritis and other rheumatic diseases.

In the field of AIDS-related research, Institute-supported researchers, utilizing a new biotechnology, have been able to detect minute quantities of human immunodeficiency virus (HIV) in skin biopsy tissue specimens. This can enhance the safety of skin grafting procedures. Other NIAMS-supported researchers have reported that zidovudine (AZT) can cause psoriasis to regress in HIV-infected individuals. This paves the way for a better understanding of the cause of psoriasis as it relates to the body's immune system.

Finally, I want to mention the comprehensive collaboration between the NIAMS and the Department of Defense to study skin, rheumatic, and musculoskeletal manifestations of disease in Army personnel who are HIV-positive. We foresee a synergism from which both agencies will benefit--as will the American people.

Mr. Chairman, the budget request for this Institute for Fiscal Year 1991 is $176,080,000. I will be pleased to answer any questions you may have.

BIOGRAPHY OF DR. LAWRENCE E. SHULMAN

July 25, 1919, Boston, Massachusetts

Education: Harvard University, A.B., 1941; Yale University Graduate School, Ph.D., 1945; Yale University School of Medicine, M.D., 1949.

Professional History: 1949-50, Intern, Medicine, The Johns Hopkins Hospital, Baltimore, Maryland. 1950-51, Ayerst, McKenna and Harrison Fellow in Endocrinology, The Johns Hopkins University School of Medicine. 1951-52, Vernon D. Lynch Fellow in Internal Medicine, The Johns Hopkins University School of Medicine. 1952-53, Assistant Resident, The Johns Hopkins Hospital. 1954-present, Physician, The Johns Hopkins Hospital. 1955-75, Director, Connective Tissue Division, Department of Medicine, The Johns Hopkins University School of Medicine. 1960-66, Physician-in-Charge, Arthritis Clinic, The Johns Hopkins Hospital. 1956-67, Physician-in-Charge, Connective Tissue Clinic, The Johns Hopkins Hospital. 1966-69, Physician-in-Chief, Division of Chronic and Community Medicine, The Baltimore City Hospitals, Baltimore, Maryland. 1970-73, Associate Professor of Medical Care and Hospitals, The Johns Hopkins University School of Hygiene and Public Health. 1964-present, Associate Professor of Medicine, The Johns Hopkins University School of Medicine. 1976-80, Acting Associate Director for Arthritis, Musculoskeletal, and Skin Diseases, National Institute of Arthritis, Metabolism, and Digestive Diseases. 1980-83, Associate Director, Arthritis, Musculoskeletal and Skin Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. 1983-1986, Director, Division of Arthritis, Musculoskeletal, and Skin Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. 1986, Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases. 1987-present, Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Professional Organizations: American Association for the Advancement of Science, American College of Physicians, American Federation for Clinical Research, American Rheumatism Association (President, 1974-75), American Society for Bone and Mineral Research, The Arthritis Foundation, Brazilian Society of Rheumatology, Carla Curzio Neapolitan Society, Lupus Foundation of America, New York Academy of Science, Pan American League Against Rheumatism (President, 1982-86), Society for Clinical Trials, Sydenham Society, Society for Investigative Dermatology.

Honors, Awards: Senior Investigator Award, The Arthritis Foundation, 1957-62. Pemberton Memorial Lecture, 1963. Fellow, American College of Physicians, 1967. Wallace R. Graham Memorial Lecture: Toronto, 1973. The Heberden Medal for Research in the Rheumatic Diseases, Heberden Society, London, 1975. Distinguished Service Award, The Arthritis Foundation, 1979. Honorary Member, Brazilian Society of Rheumatology, 1980. Honorary Member, Chilean Society of Rheumatology, 1981. Knowles Lecture: San Francisco, 1982. Honorary Member, Costa Rican Association of Rheumatology, 1984. Honorary Member, Australian Rheumatism Association, 1985. The Public Health Service Superior Service Award, 1985. National Lupus Hall of Fame, 1986. Elected Master, American Rheumatism Association, 1987. Honorary Member, Swiss Society of Rheumatology, 1987.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. Dr. Shulman, thank you very much for your statement. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

PROGRESS AND PLANS FOR THE 1990'S

Question. Five years ago the creation of a separate Arthritis Institute was a matter of considerable controversy. Your Institute is a little over 4 years old. Could you give the Committee a status report on the progress made since you were created as a separate Institute, and what your research plans are for the 1990's?

Answer. Over the period of the past 4 years, the Institute has provided increased leadership and direction for research on arthritis and musculoskeletal and skin diseases, and this has had a significant and direct impact on the number and quality of research project applications considered for funding by the Institute.

Of particular note are expansions in the breadth and scope of the research centers program. Nine new Specialized Centers of Research--three each in rheumatoid arthritis, osteoarthritis, and osteoporosis--have been established, as well as two new core research centers in skin diseases.

The extramural Musculoskeletal Diseases Program has expanded to two sections--one focusing on bone diseases and bone biology, and the other on fracture healing, athletic injuries, low back pain, and rehabilitation.

Additional efforts in epidemiology and prevention have been possible. Important collaborative epidemiology projects are under way with the Soviet Union, comparing disease incidence and prevalence in related populations in the United States and the U.S.S.R. Patient and public information programs have been expanded and improved. For example, a task group on Lupus in Minority Populations has been meeting on a regular basis to develop new educational materials for patients and health professionals. The National Arthritis and Musculoskeletal and Skin Diseases Clearinghouse has become a separate entity, and it provides a new focus for many of these efforts.

Our interaction with other related programs has been enhanced. The NIAMS now has separate representation on many coordinating committees, including the Prevention Committee, the Nutrition Committee, the Committee for the Assessment and Transfer of Technology, and the Orphan Diseases Committee. We have contributed to the reports prepared by these groups, and we have effectively coordinated our programs with related efforts in other agencies. Interagency coordination has been further increased through two interagency committees--one on arthritis and musculoskeletal diseases and one on skin diseases--both chaired by the Institute Director.

The Institute has begun new efforts to study rheumatic disease and skin disease manifestations in patients infected with the HIV virus, and this is likely to provide new clues on the pathogenesis of these diseases. A collaborative effort has been established between the NIAMS and the U.S. Army to study skin manifestations of AIDS.

The Intramural Program has added two new components--an Orthopaedic Research Unit and a Laboratory of Skin Biology. The Laboratory of Skin Biology will serve as the focus for expanded research and training possibilities for explaining normal and pathological processes in the development and function of the skin. The Orthopaedic Research Unit is developing well, and we plan to provide continued support for this program. A group to work on fundamental bone and connective tissue biology is also planed.

An increased number of representatives specifically related to the mission of the Institute now serve on the National Advisory Council, which reviews and approves grant applications for funding consideration, and on the National Advisory Board, which provides advice on the Institute's plans for an expanded and intensified research effort on arthritis and musculoskeletal and skin diseases. This has improved the quantity and quality of outside advice available to the Institute.

The NIAMS has conducted a number of workshops, conferences, and meetings in which research advances and opportunities for research in the 1990's were considered and discussed. For example:

o In October 1986, the NIAMS and its National Advisory Board sponsored a centennial conference on "Molecular Biology: Its Potential for Advancing Rheumatology Research." Following the conference, a panel of senior scientists met to consider areas of research that would benefit most rapidly from advances in molecular biology.

o In 1988, the NIAMS and the NIAID sponsored a highly productive scientific workshop on Lyme disease at which leaders in the field discussed the pathogenesis, diagnosis, treatment, epidemiology, and prevention of Lyme disease. Areas of research needing further effort were reviewed in a postworkshop session.

o Also in 1988, the NIAMS and the American Academy of Orthopaedic Surgeons sponsored a scientific workshop on "New Directions in Low Back Pain Research." The workshop served to assess recent progress in low back pain research and to develop directions for future studies.

o In 1989, a scientific workshop was held on "Inflammation and Sports-Induced Tissue Injury" to discuss the current state of the art in treating injuries and to develop recommendations for future areas of study.

o In February 1990, the Institute participated in a major scientific workshop on osteoporosis and convened a meeting with leading investigators immediately thereafter to develop research recommendations.

o The NIAMS has organized a broad-based scientific workshop on "Heritable Disorders of Connective Tissue" to be held in April 1990. The workshop will allow basic scientists and clinicians working on these disorders to discuss new developments and research initiatives.

OSTEOPOROSIS

Question. I understand that the sodium fluoride treatment for osteoporosis was found not to be effective and, based on your research, the FDA has disapproved this drug treatment. Also as you know, the Committee asked for a report, due not later than June 30, on all efforts focused on reducing the prevalence of osteoporosis. What can you tell us about the progress on that study as well as the progress generally on reducing the prevalence of osteoporosis?

Answer. Senate Committee Report No. 100-127 directs the Department to undertake a detailed review of the programs of research, public and professional education, and health promotion aimed at reducing the prevalence of osteoporosis. The report also requests recommendations for future directions on osteoporosis. Responsibility for the preparation of the report has been assigned to our Institute, the NIAMS, and the report is being prepared under the aegis of the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee, chaired by the Director of the Institute.

Each member of the committee has been asked to report a list of Agency projects/programs in osteoporosis, an overview of program goals and recommendations for future directions in these areas, and a summary of funding for FY 1989. In addition, the February 1990 scientific workshop "Research Advances in Osteoporosis" provided a review of the latest information from basic and clinical research, and set the stage for continued work in this area. A set of research recommendations developed at this workshop will accompany the report.

The prevalence of osteoporosis increases with age; 90 percent of women 75 years of age and older have moderate or severe osteoporosis. The lifetime risk of hip fractures in white women is as great as the risk of breast, endometrial, and ovarian cancers combined. Twenty percent of all hip fractures contribute to death within 1 year after fracture. Osteoporosis is more prevalent in whites than in blacks. Progress has been made in understanding why the prevalence in black persons is lower than in white persons. The turnover of bone is less in blacks as compared to whites. Research has shown that blacks develop a 10 percent higher adult peak bone mass than do whites, and this provides some protection from osteoporosis. Unraveling the details of this metabolic phenomenon may lead to a new conceptual approach to the prevention or treatment of osteoporosis. Inadequate calcium intake can be a contributing factor to the bone loss of postmenopausal women and the elderly.

There are few reliable data on the prevalence of osteoporosis and the incidence of related hip fractures in different countries and ethnic groups. The NIAMS is collaborating with the World Health Organization and the National Institute on Aging to conduct a major epidemiologic study to determine if the rates of osteoporosis and fractures vary among the countries. Differences between groups may indicate genetic or environmental risk factors, and such differences may suggest new approaches to treatment and prevention. The study complements the ongoing Third National Health and Nutrition Examination Survey, conducted by the National Center for Health Statistics.

OSTEOARTHRITIS

Question. Osteoarthritis is by far the most common type of arthritis in the elderly, and there is no effective prevention or treatment. Is the research at a stage where a commitment of substantial additional funds could provide some important advances?

Answer. In osteoarthritis, joint cartilage cracks, then becomes thin, and may later erode, leaving the ends of bone unprotected. Deterioration of cartilage is the key feature in the joint affected by osteoarthritis. Although progress has been made in understanding this deterioration, a number of questions remain unanswered.

Two critical areas that NIAMS grantees are actively pursuing are the initiating events and the detailed steps that follow that event in producing osteoarthritis. Investigators are studying the normal properties of cartilage and how these change in disease. In a recent advance, researchers have identified a new type of collagen, type IX, that serves as a glue for type II collagen, the mainframe of cartilage. It is possible that abnormalities in type IX collagen may be responsible for the cartilage damage seen in osteoarthritis.

Although obesity is generally recognized as a risk factor for osteoarthritis, researchers are moving away from considering it a "wear and tear" disease. Many elderly people never develop osteoarthritis, indicating that other factors are at work in this disease. There are clear examples of osteoarthritis developing in a specific joint, such as the knee, that is injured while engaging in sports, such as football or basketball. On the other hand, other sports, such as long-distance running, do not necessarily induce osteoarthritis in weight-bearing joints.

Bone mass is being measured in patients with primary osteoarthritis of the hip who are to undergo total hip replacement. Research has shown that those with reduced bone mass are more prone to microfracture and to loosening of the prosthesis after the hip is replaced. The NIAMS supports research to develop new and more durable biomaterials for his prostheses.

The Cooperative Systematic Studies in the Rheumatic Diseases, a consortium of clinical centers supported by contract, is currently conducting a clinical trial on the treatment of osteoarthritis of the knee. The clinical trial is evaluating the relative efficacy of analgesics vs. anti-inflammatory drugs in the treatment of osteoarthritis.

In February 1988, the NIAMS submitted to the Senate a plan for expansion of the intramural program. Among the highest priority in the plan is an area of science important to the further understanding of osteoarthritis -- the establishment of a new basic research laboratory on connective tissue biology.

The Institute is funding three Specialized Centers of Research on basic and clinical research on osteoarthritis. These centers concentrate research personnel in a multidisciplinary environment, providing resources and facilities for advanced approaches to both laboratory and clinical science. By promoting active collaborations among investigators the centers provide increased momentum and leadership to the national research effort. Scientists in the osteoarthritis centers are investigating osteoarthritis as the failure of the entire joint (which includes the joint lining, bone tissue, ligaments, and neuromuscular elements), the biochemistry of cells in joint cartilage, and the effects of physical and growth factors on cartilage.

Early osteoarthritis is characterized by articular cartilage matrix alterations and increased chondrocyte metabolism. There are also changes in the synovium, the joint lining, and subchondral bone. The interrelationships among these events are unclear. It is also unclear whether the primary lesion occurs in cartilage or subchondral bone. Recently, a novel technique of microscopic computed tomography (micro CT) was developed to assess the three-dimensional architecture of small samples of bone. Using micro CT, investigators found that trabecular bone in the subchondral regions, just below the cartilage, had thicker trabeculae that were closer together than those in control samples. From this animal model, therefore, it appears that trabecular remodeling may be an early event in osteoarthritis. Uncovering the early events in this disease is clearly important for developing effective prevention and treatment strategies.

The NIAMS and the National Institute on Aging issued a program announcement on osteoarthritis to the research community in April 1988. This announcement seeks to stimulate multidisciplinary research on epidemiology, etiology, prevention, and treatment of osteoarthritis. Both basic and clinical studies are encouraged, and applications are being received on a continuing basis. A commitment of additional funds could accelerate research in this field and provide some important advances.

LYME DISEASE

Question. One of the problems with Lyme disease, as you know doctor, is the difficulty in diagnosing the disease. Do we now have an adequate diagnosis for Lyme disease?

Answer. The diagnosis of Lyme disease is a difficult one because the causative agent, Borrelia burgdorferi, is usually not easily cultured or directly observable from patients' specimens. Currently available standard laboratory tests are not fully satisfactory in that they lack sensitivity and specificity.

I am pleased to report that new laboratory tests of greater accuracy, reliability, and sensitivity are being developed. One involves use of highly sensitive antibody tests to detect presence of the causative agent in urine. Another utilizes the polymerase chain reaction to identify small numbers of bacteria in the diseased tissues. A recent report described the ability to culture the bacteria from the blood of patients with Lyme disease. Another recent study reports the successful uncoupling of immune complexes to increase the sensitivity of antibody tests.

Question. Could you comment on the issue of underdiagnosis or overdiagnosis of Lyme disease?

Answer. Lyme disease is often underdiagnosed in parts of the country where it is not endemic or is relatively uncommon. Lyme disease can present with a wide variety of signs and symptoms, making it difficult for physicians with little or no experience with it to make the correct diagnosis. On the other hand, in parts of the country where Lyme disease is well established and where there has been extensive publicity, patients with signs and symptoms suggestive of Lyme disease may be diagnosed inappropriately as having the disease when in fact they have some other disease resembling it.

Both aspects of this problem could be addressed by more sensitive, accurate, and inexpensive diagnostic tests. In general, serologic (antibody) tests currently available usually do not pick up some cases in early Lyme disease; but on the other hand, in the later stages of the disease the tests are often too sensitive and less specific. Recently, there has been great progress on developing new and more accurate diagnostic tests for Lyme disease. New tests include a more specific antibody test in urine, identification of bacterial components in tissue by polymerase chain reaction, and the uncoupling of antibody complex for better recognition of the antigenic site.

Question. In what proportion of Lyme disease cases do serious complications develop?

Answer. In the United States, 60 percent of Lyme disease patients develop arthritis, primarily in the large joints, and this is often disabling. Approximately 15 percent of patients have varying disorders of the nervous system that can include headache, facial palsy, nerve root pain, meningitis, and motor abnormalities; and 8 percent have cardiac complications, including interruption of the heart's rhythms.

Question. Have you been able to pursue some of the recommendations for research that came out of your December 1988 scientific workshop?

Answer. We are pleased to report that as a result of the December 1988 scientific workshop, the NIAMS, in conjunction with the NIAID, issued a joint request for applications to encourage research in the pathogenesis of Lyme disease. The response to this announcement was most gratifying, with 45 applications received. Twenty-one of the applications received in response to the request were in areas under the purview of the NIAMS. The review of these proposals has just been completed, and the Institute expects to fund several excellent proposals for a total of over $1,000,000.

In addition, the NIAMS issued a program announcement last summer for Clinical and Epidemiologic Research in Lyme Disease.

Those applications responding to this announcement are being accepted and reviewed on a continuing basis. The anticipated epidemiologic studies will determine the prevalence and incidence of Lyme disease. Efforts will be made to define risk factors in certain individuals who appear to be particularly prone to developing the late manifestations of the disease. Overall, we expect to support research on Lyme disease in FY 1991 in the amount of $2,703,000.

PROBLEMS OF THE ELDERLY

Question. Are there activities that our senior citizens can participate in that will keep them ambulatory--and thus avoid many of the crippling musculoskeletal disorders?

Answer. Osteoarthritis is the most common among the many joint disorders of the elderly. The hip, knee and hand are the sites most frequently associated with disability. Risk factors include obesity, major injury, and repetitive use associated with occupational activity. Weight reduction and job performance modification may either be protective or prevent progression of osteoarthritis. Preventive strategies have focused on disease management to minimize or prevent physical disability and to enhance capacity for activities of daily living. Examples include special exercises and innovative devices to assist daily activities, and medicinal and nonmedicinal measures for pain reduction.

Osteoporosis is a common condition in which bone mass decreases and causes bones to be susceptible to fracture. It increases in frequency with age; 90 percent of women 75 years of age and older have this condition. In general, active women especially those who engage in weight bearing exercise have a higher bone mass than sedentary women and thus a lower incidence of osteoporosis. There are three periods in a woman's life when exercise may play a role in preventing osteoporosis: 1) adolescence through young adulthood--by maximizing the growth of bone mass, (2) mature adulthood--by maintaining bone mass, and (3) postmenopause--by retarding bone loss.

Question. Is there anything to be learned from such fields as Sports Medicine in reducing the incidence of musculoskeletal disorders among our elderly?

Answer. Exercise and physical activity are important at all stages of life. While specific exercise prescription may not be precisely defined, regular moderate levels of activity programs can be suggested for most individuals. The musculoskeletal system can clearly benefit from exercise by gains in strength, flexibility, and coordination. Activity-related improvements in the musculoskeletal system, when maintained throughout life, lead to positive gains for the elderly.

It is important to achieve the highest possible level of bone mass and maintain it for life. This may help to avoid osteoporotic fractures in one's senior years. A well-maintained musculoskeletal system may be important in both avoiding falls and making protective responses, should a fall occur. For osteoarthritis, non weight-bearing exercise may help to retain strength and range of motion in affected joints.

SPACE EXPLORATION

Question. Are you doing any research to support our space program with regard to the special situations resulting from the reduction of gravitation force?

Answer. The NIAMS supports substantial research related to the muscle loss that is due to inactivity or reduced work load. These have many similarities to a reduced gravity environment. A vital impetus for this research is the rapid loss in muscle tone and muscle mass when people are at bed rest, because of either injury or disease. Studies on muscle involve elucidating the molecular mechanisms that take place when particular muscles are not being used. Preliminary results indicate that stages in the feedback cycle can be disrupted by certain hormone-like drugs. This has the potential for reducing the rate of muscle atrophy.

Another important aspect involves studies on the response to exercise and the way muscles build up following repetitive exercise. By combining knowledge from the different research approaches, scientists should be able to devise exercise strategies to maintain astronauts close to optimal muscular tone in the special environment of space capsules.

Significant loss of bone is another serious consequence of space flight or prolonged bed rest (in excess of 2 weeks). The loss of bone mass results in a condition that is similar to osteoporosis. Numerous grants supported by the NIAMS are concerned with the structure and remodeling of bone in response to various states of mechanical loading. One particularly interesting technology is called micro-CT, which allows investigators to study nondestructively the fine structure of trabecular bone as it changes its architecture with various degrees of loading and unloading.

The NIAMS staff are coordinating with members of the staff of NASA on early design of projects for future space flights. In fact, an NIH/NASA scientific workshop to discuss issues of bone loss and muscle loss in space is now being planned for next year.

INTRAMURAL RESEARCH

Question. Dr. Shulman, last year we discussed the growth in your intramural research program which was approximately 5 percent of the total of your effort compared to an 11 percent NIH average. What progress are you making in building a solid intramural program?

Answer. Two new laboratories have been created consistent with the priorities suggested by an ad hoc expert advisory committee on the future growth of the intramural program. First, a Laboratory of Skin Biology headed by Dr. Peter Steinert, an internationally renowned protein chemist and cell biologist, will serve as the focus for expanded research and training possibilities for elucidating normal and pathological processes in the development and function of the skin. Second, a Laboratory of Structural Biology Research, headed by an outstanding electronmicroscopist, Dr. Alasdair Steven, will emphasize the application and development of exciting new techniques for enhancing the images of molecules from muscle, skin, connective tissue and bone--molecules of particular relevance to the primary missions of the NIAMS.

This year we will add our first Biomechanics Research Fellow, and this will strengthened our program with the Biomechanics Laboratory of the Clinical Center. The new Orthopaedics Research Unit received a highly favorable review at a recent meeting of our Board of Scientific Counselors. We plan to provide continued support for this program. The Counselors strongly recommended that a scientific group working in fundamental bone and connective tissue biology be added to this group. This is now our highest priority for the future.

SUNLIGHT AND SKIN

Question. Dr. Shulman, would you share with us the recommendations of the NIH Consensus Development Conference on Sunlight, Ultraviolet Radiation, and Skin that you held last May?

Answer. The Consensus Development Conference panel of experts has issued their final statement with recommendations regarding the prevention and treatment of the adverse effects of sunlight exposure and ultraviolet (UV) radiation on the skin. Among their findings and conclusions are the following:

o UV radiation produces a variety of pathologic effects, including sunburn, pigmentary changes, immunologic alterations, and neoplasia.

o The risk of UV radiation damage to the skin can be prevented or reduced by wearing proper clothing, using a physical or chemical sunscreen with a sun protection factor rating of at least 15, and modifying schedules of outdoor activities to avoid the peak exposure times between 10 a.m. and 3 p.m.

o There is a need to better educate the public regarding the hazards of tanning parlors. There should be better regulation of tanning facilities to protect the public against unintentional exposure.

o Sunlight-induced adverse skin alterations can be treated by standard surgical techniques and superficial modalities.

o There is insufficient evidence at this time to recommend the use of Retin-A or similar compounds to treat or reverse the effects of sun-damaged skin.

The Consensus Panel made a number of recommendations for further research on the effects of sunlight on the skin. The main recommendations follow:

o Further research to define the immunologic effects of UV radiation on the skin.

o Additional research on the differences between sun-induced aging and chronologic aging.

o The development of a more current database on the incidence of non-melanoma skin cancer.

o Further research to define the action spectrum of sunlight and UV radiation in the pathogenesis of melanoma.

o Further research on the biologic effects of UVA radiation particularly in regard to its "photoaging" and immunologic effects.

o New approaches to diminish the risk of sun exposure in childhood and adolescence including such things as behavior modification and education.

o The development of more effective sunscreens and the monitoring of the risk/benefit ratio of the widespread, long-term use of sunscreens.

INFECTIOUS ETIOLOGY OF RHEUMATIC DISEASE

Question. What progress has been made in the search for a possible infectious agent as a cause of rheumatoid arthritis?

Answer. The Institute has been and continues to be deeply interested in infectious agents as possible causes of rheumatoid arthritis and other rheumatic diseases. Research over the past decade has yielded interesting leads regarding a possible infectious agent as a cause of one or another rheumatic disease. For example:

o A parvovirus has been found in some patients with rheumatoid arthritis. The immune system of patients with rheumatoid arthritis is known to respond poorly to Epstein-Barr virus. Mycoplasmas are a cause of arthritis in some animal species.

o Recent studies have revealed a similarity between binding sites for various bacteria and binding sites for IgG rheumatoid factor.

o Lyme disease is known to be caused by the spirochetal bacteria Borrelia burgdorferi and, if untreated, can lead to chronic arthritis that resembles rheumatoid arthritis. The cause of the arthritis is not yet clear.

o Epidemiological studies suggest that arthritis of the spine may be triggered by an immune response to bacterial infection, and this antibody response may cross react with normal components of the body resulting in inflammation.

o A chronic, erosive arthritis that resembles rheumatoid arthritis can be induced in susceptible rats by inoculation with fragments from specific bacteria.

o Following infection of the nasopharynx by Epstein-Barr virus, the virus remains latent in cells of the salivary gland.

Increased levels of virus DNA can be found in the gland of patients with Sjogren's syndrome, an autoimmune disease often associated with rheumatoid arthritis. It has been suggested that the virus may become reactivated and provide a trigger for an autoimmune attack on the salivary gland.

o The cellular binding site for streptococcal protein G is related to sites that bind human rheumatoid factors. The relationships between rheumatoid factor and microbial IgG-binding proteins may be important for understanding the generation of rheumatoid factors.

The Institute issued a program announcement in February 1988 to the medical scientific community inviting additional research grant proposals to stimulate a more intensive search for infectious agents as initiating or contributing factors to the development of rheumatic diseases. We are pleased to report that, as a result, several new research grant applications have been submitted, and they are currently under consideration.

The Institute has held a number of conferences at which the possible infectious etiology of rheumatic diseases was discussed. A December 1988 conference on Lyme disease lead directly to the NIAMS and the NIAID issuing a request for grant applications on the Pathogenesis of Lyme Disease and several related program announcements. Most recently, in January 1989, a multidisciplinary conference was held on Sjogren's syndrome. The possible infectious etiology of Sjogren's syndrome was discussed, and research in this area is being pursued.

In FY 1990, the Institute will begin a multicenter clinical trial to assess the safety and efficacy of minocycline therapy in 200 volunteers with rheumatoid arthritis. Researchers have shown that minocycline, a form of tetracycline, inhibits the activity of collagenase in joint tissues and synovial fluid. Collagenase, an important constituent of connective tissue and joint cartilage, is increased in the joints of patients with rheumatoid arthritis, and this causes joint damage.

Question. Is there any relationship between the mycoplasma that has been suggested as a cause of rheumatic diseases and the newly discovered mycoplasma that may play a role in the infectious complications of AIDS?

Answer. There is no evidence of such a relationship at this time. Although it has long been hypothesized that mycoplasmas play a role in rheumatoid arthritis in humans, numerous attempts over the past 30 years to cultivate mycoplasmas from human rheumatoid arthritis tissues have been, for the most part, unsuccessful.

INTRAMURAL RESEARCH

Question. We understand that the Director of NIH has allocated additional intramural space to your Institute -- how do you plan to use it, and do you have the scientific manpower to expand intramural research?

Answer. Some new space is expected to be available by the end of FY 1990, and this will be used to house a part of two new laboratories--the Laboratory of Skin Biology and the Laboratory of Structural Biology Research. Additional new space has been promised for 1 year later, and this will permit completion of our plans for the Laboratory of Skin Biology. Once the laboratories are set up, additional scientists will be recruited to staff these new efforts.

Question. Several years ago we heard from the orthopaedic research community that there was a need for an orthopaedic intramural research program. How is this effort progressing, and what are your future plans for the orthopaedic intramural research program?

Answer. Our Orthopaedic Research Unit is now located in the NIH Clinical Center, where it occupies contiguous space with our intramural Arthritis and Rheumatism Branch. This allows full interaction among our scientists. The past year has been a particularly productive one for our orthopaedic intramural research program. We plan to further strengthen this group's capacities for research and training by adding a substantial Laboratory of Bone and Connective Tissue Biology.

Investigators are carrying out research at the cellular and molecular level on the pathophysiology of bone formation, remodeling, and repair. Initial investigations have focused on the structure and function of bone and cartilage extracellular matrix proteins, and the regulation of gene expression in fracture healing. A rat model for study of bone healing has recently been developed. This model provides an excellent tool for future study of impaired fracture healing.

In examining the role of growth factors in regulating bone repair, our scientists recently demonstrated that transforming growth factor beta and fibroblast growth factor are important regulators of cartilage formation and ossification. In future work they will attempt to characterize the mechanisms responsible for this regulation. Their future plans also call for study of the origin and differentiation of bone forming cells, called osteoblasts.

EPIDERMOLYSIS BULLOSA

Question. Dr. Shulman, do you have any new research findings to share with us on epidermolysis bullosa, a group of devastating blistering diseases?

Answer. There are a number of new research findings concerning epidermolysis bullosa (EB). The first, and possibly very significant finding, is the uncovering of an animal model for the recessive dystrophic form of epidermolysis bullosa. This model consists of inbred white alpine sheep discovered in Switzerland. These animals seem to develop an exact duplicate of the human disease. Both the clinical findings and the ultrastructural examination of the animal's skin seem identical to that of the human disease; i.e., the absence of anchoring fibrils and type VII collagen. If this proves to be so, the animal model will facilitate further research into mechanisms of the disease and also into potential treatments.

Further research concerns mechanisms of attachment of the epidermis to the dermis through the basement membrane zone, which is defective in EB. Advances include the determination that the anchoring fibrils, which consist of type VII collagen and which are defective in the dystrophic form of EB, can be elaborated by the epidermal cells above the basement membrane. This was not an expected observation, as collagen is considered to be a product of fibroblasts that are normally found in the dermis below the basement membrane. This has great implications for treatment using techniques such as cultured epidermal sheets.

Acquired EB, a type of EB in which antibodies are produced to type VII collagen, has provided the source of these antibodies for use in determining exactly how anchoring fibrils function in attaching the epidermis to the dermis. They have been used to show that the end of the type VII collagen, which is not readily visible via electron microscopic examination, is found in the lamina densa of the basement membrane zone, whereas the visible banded portion of the type VII collagen is in the upper part of the dermis below the basement membrane itself. This investigation is helping us to understand how these molecules work to attach the epidermis to the dermis.

The Epidermolysis Bullosa Registry has now collected enough patients for specific epidemiologic and molecular genetic research projects. In one study, recessive dystrophic EB patents were genotyped. These patients demonstrated a higher than expected association with certain HLA markers. This may eventually aid in the localization and later isolation of the gene causing the disease. In another study, the Dowling-Meara form of EB seems to be in high enough prevalence within the registry data to make a reverse genetic linkage analysis feasible to search for the gene. The registry material is being analyzed to determine whether a full-blown genetic linkage analysis is reasonable at this time. The availability of patients through the registry should facilitate a much more efficient mounting of clinical trials when appropriate promising agents become available in the future.

SEPARATE ARTHRITIS INSTITUTE

Question. Five years ago the creation of a separate Arthritis Institute was a matter of considerable controversy. Please give us your assessment of the benefits that have come from your separating from your parent Institute. Have there been negative effects?

Answer. The NIAMS has been operating as a separate Institute since FY 1987. Creation of the NIAMS has resulted in greater visibility and focus on the national effort to combat arthritis and musculoskeletal and skin diseases.

During this time, the staff has expanded from a core of 67 persons, including an intramural program of 46 to a staff of 116 with 57 intramural scientists. This increase of staff devoted to the planning, directing and execution of research specifically on arthritis and musculoskeletal and skin diseases has allowed for a more intense effort in identifying and promoting recent research advances and in developing promising areas for new research efforts.

Some of these areas, such as sports medicine and exercise physiology, have only been taken up only in the last several years. Work on osteoporosis has expanded significantly. Because of these new responsibilities, this year the musculoskeletal diseases program was split into two sections and a separate program director hired for the section on bone diseases and bone biology.

The NIAMS has established an Office of Prevention, Epidemiology, and Clinical Applications responsible for disease prevention and health promotion activities, clinical studies, and epidemiologic projects. This office also provides a focus for international programs, orphan diseases, nutrition, and research on AIDS.

The authorizing legislation directed the Secretary, DHHS, to establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee, a Skin Diseases Interagency Coordinating Committee, a National Advisory Board to provide programmatic advice and a National Advisory Council to review and approve grant applications. These committees and boards have improved the quantity and the quality of advice by allowing for representation from a broader array of fields resulting in more specialized review.

The Intramural Program has added an Orthopaedic Research Unit and a Laboratory of Skin Biology. The Laboratory of Skin Biology will serve as the focus for expanded research and training possibilities for explaining normal and pathological processes in the development and function of the skin.

A downside has been the difficulty in obtaining increased resources to match the excitement and enthusiasm generated through focused programs on these diseases. In real terms, the budget for the Institute has increased only 2 percent since 1987, the year the Institute was established. Because of the diversity and broad range of the programs of the Institute, and the identification of important needs in areas that were previously underserved, many research opportunities highlighted through our increased planning efforts have not been able to be implemented.

EFFECTS OF TIGHT FUNDING

Question. In FY 1989 you funded 185 competing awards out of 657 eligible applications, for an award rate of 28.2 percent. What do you hear from researchers in your fields of interest about the effects of tight funding?

Answer. The estimated award rates for FY 1990 of 18.5 percent and 19.3 percent for FY 1991 are causing concern among researchers in our fields. The probability of less than a one-in-five chance of being funded compared to last year's more than one-in-four is discouraging young investigators from pursuing a career in biomedical research.

As you can well appreciate, there is considerable discouragement among researchers for several reasons. For those fortunate enough to be funded, fiscal restraints are restricting the scope and purpose of the projects. Some of our best researchers are being excluded, and researchers are forced to spend an inordinate amount of time seeking alternative sources of funds. A parallel restriction on income derived from patient care activities is forcing medical schools to withdraw supplementary funds that were available to support investigators between grants. Thus, many who do not succeed on initial application drop out of the field.

An additional problem is the way in which tight funds qualitatively restrict research. Applications have become extremely conservative, because highly innovative proposals are unlikely to be favorably reviewed and funded. Applications also must be narrowly targeted in order to produce results quickly, in time for renewal of the grant. This restricts work on long-term illnesses. Funds for multi-year therapeutic trials, even for long-term illnesses, are in extremely short supply.

Question. How do you assess whether young investigators are being discouraged from pursuing research careers?

Answer. There are several indications of reduced interest by young investigators. The first is the statement by the students themselves who indicate that watching their mentors' anxiety about grants or retirement from the research field because of failure to receive a grant is very discouraging. A second is the application rate of students to active research programs in medical schools that, by reports of investigators, is decreasing nationwide. A third is, indirectly, the decrease of applicants to medical schools that is not compensated by an increase in applicants to graduate schools in biomedical sciences.

RESEARCH CENTERS PROGRAM

Question. Do your centers programs, such as those for arthritis and for skin diseases, have enough funding to be able to exploit fully the specialized research opportunities that the center mechanism offers?

Answer. The FY 1991 budget request for centers is at the same level as in FY 1990. The request is not sufficient to fund these programs fully, and it will necessitate downward negotiations of 17 percent from the recommended level of funding. These reductions have necessitated limiting the scope of proposed research.

The Centers Program consists of 14 Multipurpose Arthritis and Musculoskeletal Diseases Centers, 9 Specialized Centers of Research (SCORs), and 2 Skin Diseases Core Centers. With the current level of funding, the Institute is unable to consider any growth of the program. The newest component, the Skin Diseases Core Centers, was originally planned for 6 centers as a start, but only 2 could be funded. The National Advisory Board continues to recommend that at least 6 Skin Diseases Core Centers be funded.

The SCORs have made remarkable progress in the three specified areas of osteoporosis, osteoarthritis, and rheumatoid arthritis. These program utilize interrelated research projects to promote interactions and new research directions. With current funding, the Institute cannot expand this valuable program to other diseases as recommended by its external advisors.

The Multipurpose Arthritis and Musculoskeletal Diseases Centers have remained a popular and competitive research mechanism. In the past 2 years, the Institute has been able to fund only three of six highly meritorious applications for such centers.

MUSCULOSKELETAL FITNESS AND SPORTS MEDICINE

Question. Dr. Shulman, what plans does your Institute have for addressing the challenge of research on musculoskeletal fitness and sports medicine?

Answer. Guidance to reduce risk of injury is important for the millions of Americans who participate in exercise programs and sports. In 1987, the NIAMS issued a program announcement to stimulate research in Sports Medicine and Musculoskeletal Fitness. A large response has led to funding of many new projects over the past 2 years.

The NIAMS is encouraging research in these areas. In the spring of 1989, we held a workshop on inflammation generated by sports-induced tissue injury, and a book summarizing the proceedings will be published shortly. Included are recommendations for future areas of study, on the basis of which we are planning to issue a program announcement to stimulate further research in this important field.

Knowledge of musculoskeletal injuries resulting from sports is insufficient. Uniform, valid, and reliable data are needed. The NIAMS plans to develop a multicenter registry for athletic injuries to assess frequency of occurrence and identify risk factors. Registry data could be translated into improved injury prevention.

RESEARCH TRAINING

Question. Are you satisfied with the size and quality of the pool of young investigators who are in training to do research in the areas of your Institute's responsibilities?

Answer. We are generally satisfied with the quality of the young investigators that this Institute supports. However, we are concerned that the number of research trainees for FY 1991 will be supported at the same dollar level available in FY 1990. Furthermore, the number of trainees has decreased significantly over the years.

Maintaining a cadre of skilled scientific investigators is critical to the missions of the Institute. The size of the pool of young investigators is insufficient in light of the numerous exciting research opportunities and missions of our Institute. Specifically, we need more young persons properly trained in the modern scientific methodologies of molecular and cell biology. Additional research trainees are needed. Even more critical is an expansion in research career manpower awards.

NATIONAL PLAN

Question. What can you report to us about the status of the national plan?

Answer. This year the Institute will initiate a major new planning process. The multi-year process will consist of a comprehensive review of research progress and research opportunities in all the disease areas under the purview of the Institute.

A steering committee of nationally prominent representatives will oversee a series of task groups in rheumatology, orthopaedics, muscle biology, bone biology, and dermatology. The steering committee will be co-chaired by the Institute Director and the Director of the Extramural Program. Following the meetings of the individual task groups, the steering committee will convene to consider the groups' recommendations and to prepare a detailed and comprehensive report.

The National Agenda will set the course--in a balanced, coordinated fashion--for future research in the diseases under the mandate of the Institute, and it will provide a framework for directing the research efforts over the next decade.

HERITABLE DISORDERS OF CONNECTIVE TISSUE

Question. I understand that there are over 100 different conditions that are included among the heritable connective tissue disorders. What research is the NIAMS supporting on these disorders.

Answer. Some of the more widely known heritable connective tissue disorders are osteogenesis imperfecta ("brittle bone" disease), Ehlers-Danlos syndrome (characterized by over-elasticity of the skin, excessive extensibility of the joints, and fragility of blood vessels), Marfan syndrome (characterized by excessive length of extremities and laxness of joints), and epidermolysis bullosa (a severe blistering disease of childhood). These disorders cut across all of our major programs.

Some of the Institute's basic research on heritable disorders of connective tissue is directed toward determining the genetic defects in patients that result in abnormalities in collagen, the principal structural protein of connective tissue. Recent advances in molecular genetics and molecular biology now make it possible to gain a better understanding of how genetic defects lead to specific clinical symptoms of each disease. For example, several defects of collagen genes have been discovered, although exactly how these genes cause the clinical disease has yet to be determined. The next level of research will be to determine the functional defect that results from each of these genetic flaws.

Type VII collagen is abnormal in the dystrophic form of EB. This defect results in separation of epidermis from dermis and the blistering seen in this disease. This is an unexpected finding because collagen is considered to be a product of fibroblasts that are normally found in the dermis. This has great implications for treatment using techniques such as cultured epidermal sheets.

In addition to the work in EB, the Skin Diseases Program is supporting research on the basis of several types of Ehlers-Danlos syndrome. Investigators in several laboratories are studying the underlying molecular basis of this defect in connective tissue. Other laboratories are investigating basic control mechanisms in the synthesis of the different forms of collagen.

Elastin is another connective tissue molecule that is under investigation. Much of this work is focused on changes that occur in the skin with chronologic aging and from chronic ultraviolet light exposure.

The NIAMS has organized a workshop to be held on April 9-11, 1990, to assess the state of knowledge concerning heritable connective tissue disorders and to set future research directions.

SYSTEMIC LUPUS ERYTHEMATOSUS

Question. Has there been any recent progress in gaining a better understanding of the pathogenesis of lupus?

Answer. Research in lupus is one of the fastest moving areas in contemporary medicine. Intensive study of the genes of lupus patients is giving a clear understanding of who gets the disease, and it is pointing to the circumstances in which patients will become susceptible. Detailed study of the way in which antibodies are made is beginning to explain the unusual self antibodies that lupus patients make. New information suggests that the basic problem of lupus patients is not that they are born to make too much antibody, but that a control mechanism of antibody formation has been injured, perhaps by an infecting agent such as a virus.

Close study of the antibody patterns and the genes, as well as of the clinical patterns demonstrated by patients, is leading to definitions of several different types of lupus, each with its own prognosis and often with its own special manner of treatment. With this information, treatment is much more carefully tailored to individual patients than it has been in the past.

To a large part, attention is now turning to the understanding and treatment of the long-term problems of lupus that were not considered possible as recently as a decade ago. Physicians are now dealing with problems of child bearing, joint replacement, recovery from kidney failure--with or without renal transplantation--and unusual atherosclerosis and heart disease in patients who are long-term survivors of lupus. Not only does the fact that these patients have survived long enough to develop these complications have importance, but the nature of the complications offers new clues to the type of damage that the initial insult of lupus can create. This information is also broadly applicable beyond the field of lupus to other diseases as well.

SKIN DISEASES RESEARCH CENTERS

Question. Dr. Shulman, several years ago we established a program of Skin Disease Research Centers. How many have been established? How many more were called for and not yet established?

Answer. In 1988, the NIAMS established two Skin Diseases Core Centers to coordinate and foster interdisciplinary cooperation among investigators. The original plan, developed through consultation with our external advisors and the academic dermatology community, called for a total of six Skin Diseases Centers.

Question. What is the percentage reduction from peer reviewed levels that would be expected under the President's budget, and what is the centers funding level required to pay at full funding level?

Answer. Under the President's budget for FY 1991, we will fund all research centers, including the skin diseases centers, at a level of $21,025,000--a 17 percent reduction from the full funding level of $25,331,000. Full funding would require an additional $4,306,000.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

OSTEOPOROSIS

Question. Dr. Shulman, osteoporosis afflicts an estimated 24 million Americans and costs our nation billions for health care and in lost productivity. What progress is being made on understanding and solving this troubling disorder?

Answer. Osteoporosis is the most common underlying cause of bone fractures in postmenopausal women and the elderly. It is a multifactorial disease; contributing causes include menopause, aging, calcium insufficiency, heredity, and inactivity. Osteoporosis is much more prevalent in whites than in blacks. Blacks develop a 10 percent higher adult peak bone mass than do whites, and this appears to provides some protection from osteoporosis. Recent research has shown that the turnover of bone is less in blacks as compared to whites.

Estrogen deficiency is a primary factor in the bone loss occurring in postmenopausal osteoporosis. Menopause accounts for 15 to 20 percent of total bone loss, which can amount to as much as 50 percent over the life of a woman. It is now clear that estrogen replacement therapy, begun at menopause, can significantly reduce the number of fractures caused by osteoporosis. Studies are under way to determine the best combination of estrogen and progesterone in the prevention of osteoporosis. Tamoxifen offers potential as an alternative agent to stop bone loss in women at high risk of endometrial and breast cancer.

Aging is a major factor in both decreased bone formation and decreased calcium absorption. After age 35-40, there is continued loss of bone mass. Inadequate calcium intake can be a contributing factor to the bone loss of postmenopausal women and the elderly. A reduced level of vitamin D that occurs with increased age leads to reduced absorption of calcium. Men and women at risk for bone loss are advised to take adequate amounts of calcium, preferably through dietary means.

Emphasis is being placed on prevention and on the identification of persons at high risk of developing osteoporosis. Active young women have been recently shown to have a higher bone mass than sedentary women. Weight-bearing exercise is necessary for bone health. Activities in which the muscles work against gravity, such as walking or jogging, may help to reduce bone loss. Furthermore, a well-maintained musculoskeletal system may be important in both avoiding falls and making protective responses, should a fall occur.

Levels of interleukin-1 are elevated in patients with osteoporosis, and those levels are reduced during treatment with estrogen and progesterone. Measurement of interleukin-1 may offer promise as a new marker for evaluation of the metabolic status of bone, and this may permit early diagnosis of osteoporosis. Other biochemical markers are being investigated.

The NIAMS intramural scientists have developed a useful rat model for the study of fracture healing in osteoporosis. The rat model is being used to investigate the function of osteonectin, a recently discovered protein in the extracellular matrix of bone. This protein is lacking in osteogenesis imperfecta, an inherited condition in which bones are abnormally brittle and break easily. The model is also being used to investigate the role of estrogen deficiency in osteoporosis.

More data are needed on the prevalence of osteoporosis and the incidence of related hip fractures in different countries and ethnic groups. The NIAMS is collaborating with the World Health Organization and the National Institute on Aging to conduct a major epidemiologic study to determine if the rates of osteoporosis and fractures vary. Differences between groups may indicate genetic or environmental risk factors and suggest new approaches to prevention and treatment. The ongoing Third National Health and Nutrition Examination Survey conducted by the National Center for Health Statistics is studying in detail issues concerning the prevalence and risk factors in osteoporosis.

Therapeutic agents currently under clinical study are calcitonin, bisphosphonates, and cyclic therapy. Each has potential for small increases in bone mass and possible reduction in bone fractures, and each has drawbacks in terms of side effects, cost, or patient acceptance. Sodium fluoride has the capacity to stimulate bone growth. A recently completed clinical trial at the level of 75 mg sodium fluoride per day indicates that this treatment was not effective in reducing incidence of fractures.

New areas of investigation include growth factors that influence the rate of bone resorption and bone formation and the potential of using electrical stimulation of bone growth. Transforming growth factor beta (TGF-beta), synthesized by skeletal cells, inhibits bone resorption. Researchers are attempting to develop drugs that will control the activity of these growth factors. Other potential uses of TGF-beta include accelerated fracture repair, treatment of nonunion fractures, and improved biological ingrowth of bone into porous metal implants. Investigators have treated fracture nonunions in a rat lower limb with low-level electric fields that stimulated the rate of growth and repair; the technique appears to reverse osteoporosis of the spine significantly in a rat model.

Question. How much does the President's FY 1991 budget include for osteoporosis research? How does this compare to FY 1989 and FY 1990?

Answer. The overall increase in the President's FY 1991 budget for the Institute is 4 percent. The proportion of the budget that will be allocated to osteoporosis will depend on both the quantity and the quality of research grant applications that are received. Osteoporosis is among the very highest priorities of the Institute, and we are working with the extramural community to stimulate additional, high-quality work in this field. For FY 1991, we estimate that we will spend $11.7 million. This compares with $11.3 million in FY 1990 and $11.0 in FY 1989.

RESEARCH PROJECT GRANTS

Question. Dr. Shulman, this Committee continues to be concerned about the declines in the percentages of approved research grants which receive funding. Particularly troubling has been the decline at the NIAMS. In your judgment, what are the reasons for this decline? What percentage of approved grants were you able to fund in 1990? What does that compare with the level estimated in the budget for FY 1991?

Answer. Ever since the Institute was established in 1987, we have consistently had the lowest payline of all the Institutes at the NIH. This reflects both the high quality of the research project applications received and the tight funding situation. Research on arthritis and musculoskeletal and skin diseases is at the cutting edge of modern day science, and the applications received by this Institute receive excellent priority scores from the initial review groups. The award rate for the NIAMS was 31 percent in FY 1987 and 28 percent in FY 1988 and FY 1989. It is estimated to drop to 19 percent in FY 1990 and FY 1991.

Question. Of the grants which receive funding, what do you estimate will be the rates of downward negotiation in FY 1991? How do these compare with FY 1989 and FY 1990?

Answer. The downward negotiation for competing research project grants was 12 percent in FY 1989. The level of downward negotiations is projected to remain at 12 percent under the FY 1990 budget and the FY 1991 President's budget request.

NATIONAL CENTER FOR RESEARCH RESOURCES

STATEMENT OF DR. ROBERT A. WHITNEY, JR., ACTING DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next, Dr. Whitney, the Division of Research Resources. Your Division provides important support both to the intramural and extramural research efforts. You do this through a number of mechanisms, your clinical research program which supports a network of 78 dispersed centers across the country.

Your request next year is $319.15 million, for a 5.33-percent decrease.

Dr. WHITNEY. Mr. Chairman, I am pleased to present the President's request for the fiscal year 1991 appropriation for the Division of Research Resources.

Since 1962, the Division has been responsible for providing much of the infrastructure support that facilitates the conduct of extramural research funded by the categorical Institutes of the National Institutes of Health, and other research programs supported by the Public Health Service.

The Division's six programs provide critical resources: from state-of-the-art equipment to dedicated research beds and human cells—essential to the conduct of the Nation's biomedical research.

Before turning to a brief summary of the budget request, I am pleased to announce that Secretary Sullivan recently approved the merger of the Division of Research Resources and the Division of Research Services. The new organization is named the National Center for Research Resources.

The 1991 budget request will allow the Center to continue most programs at the same level as in 1990, with some exceptions which I will briefly discuss.

In response to the Nation's changing demographics, the decline of entry into biomedical research careers, and the administration's commitment to expanding opportunities in biomedical research for underrepresented minorities, substantial increases have been requested for the two minority programs supported by the Center: The Minority High School Student Research Apprentice Program, which provides the opportunity for minority high school students to work in health-related research for 8 weeks in the summer would be increased significantly to support a total of 1,764 apprentices. The research centers in minority institutions would receive a 30-percent increase over the 1990 level. This program is designed to increase the capacity of predominantly minority, doctoral degree granting institutions to perform biomedical research.

The increase requested will allow for more emphasis on research on ethnic-specific diseases and expanded involvement in AIDS clinical trials. Also, within the request for clinical research, which supports a network of centers for the infrastructure support for high quality clinical investigation, a new effort will be initiated to encourage minority junior physicians and dentists to participate in the highly successful Clinical Associate Physicians' Program at the General Clinical Research Centers.

A modest increase has been requested in 1991 for AIDS research conducted and supported by the Center. All of the Center's programs are participating to some degree in the AIDS endeavor, with the greatest involvement in the Clinical Research Program and the Laboratory Animal Sciences and Primate Research Program, where we have recently seen some very exciting results related to the development of an AIDS vaccine.

This year's request proposes a reduced level, $17.7 million for the biomedical research support grants, a program which awards flexible funds to institutions to support biomedical research needs not served by other programs and for purposes best identified at the local level by the grantee institutions.

Within the request for this program, one-third of the funds will be targeted to increase the numbers of underrepresented minorities and economically disadvantaged persons participating in biomedical research.

PREPARED STATEMENT

Other Center activities, such as the Biological Models and Materials Research Program, the Biomedical Research Technology Program, and the Shared Instrument Program within the biomedical research support activity would be maintained at approximately the 1990 level.

The 1991 request for the extramural programs of the National Center for Research Resources is $319,151,000. I would be pleased to respond to any questions you may have. Thank you.

[The statement follows:]

STATEMENT OF DR. ROBERT A. WHITNEY, JR.

Mr. Chairman and Members of the Committee: I am pleased to present the President's request for the Fiscal Year 1991 Research Resources appropriation. Since 1962, this appropriation has provided much of the infrastructure support that facilitates the conduct of extramural research funded by the categorical Institutes of the National Institutes of Health, and other research programs supported by the Public Health Service. I am pleased to be able to tell you that the Secretary has recently approved the establishment of the National Center for Research Resources, merging the Division of Research Resources extramural programs with the Division of Research Services intramural programs.

Today I will be speaking of the extramural programs since the Research Resources budget request is entirely extramural. The Center's six extramural programs provide critical resources - from state-of-the-art equipment to dedicated clinical research beds and human cells - essential to the conduct of the nation's biomedical research. I will briefly describe each program.

The Clinical Research Program supports a network of 78 geographically dispersed centers, located within either teaching hospitals or research institutions, where scientists can study normal physiology and disease processes in both adults and children. The centers provide highly skilled research nurses, as well as specialized laboratories and support facilities for inpatient and outpatient research, to facilitate the conduct of high quality clinical research, providing the infrastructure essential for carrying out clinical trials and other types of clinical research funded by other NIH and PHS components. The centers also support the Clinical Associate Physician (CAP) program, which provides the opportunity for junior physicians and dentists to enter clinical research careers.

In 1989, more than 7,250 investigators utilized these centers for their research projects. These researchers received more than $550 million in primary research funding from the categorical Institutes of the NIH, as well as another $150 million from other sources. This national network of General Clinical Research Centers will continue to be the essential interface between basic and clinical research.

The GCRCs continue to host a wide variety of research projects, both AIDS-related and other, in children and adults, which are producing exciting results. A recent study revealed that the drug deprenyl delays the onset of disability in patients with early, otherwise untreated Parkinson's disease. Another group of investigators has developed a method for the rapid, early and definitive detection of HIV infection in infants at high risk for acquired immunodeficiency syndrome or AIDS. This will allow for early treatment of infected infants and clear others who are suspected of infection. At another center a method is being developed that may be effective in rapidly identifying early cases of Alzheimer's disease.

Within a fairly level request for the Clinical Research program, we are planning the initiation of a new program to encourage minority junior physicians and dentists to participate in a program comparable to the successful Clinical Associate Program at the centers. The first year of the program will provide support for five such positions.

Technology is the engine that drives today's biomedical research. Our Biomedical Research Technology Program provides the scientific community access to advanced technologies needed as tools to solve the problems of biomedical research. The program funds centers for the development and application of essential technologies that are not widely available. The centers are staffed by gifted scientists and engineers who work closely with biomedical scientists from academia, industry, and other laboratories both to develop and to apply new technological capabilities to cutting-edge biomedical research problems. The new technologies developed by this program have significant applications, and I will give a couple of examples.

In the molecular area, a new beam line that can be used for X-ray diffraction studies of crystalline viruses and proteins from pathogenic sources was funded in 1989 at the Cornell High Energy Synchrotron Source. This will be the only synchrotron facility in the world with a biological containment capability to permit the structural studies of crystalline infectious agents such as poliovirus and coat proteins from the AIDS virus and its receptors. A different type of structural research collaboration between a scientist at the University of California, Berkeley, and the mass spectrometry center in San Francisco resulted in the determination of the chemical nature of the signalling mechanism used by bacteria to control the proteins involved in their motion. The chemical basis for cellular motility is a major unsolved problem in cell biology; if this signalling mechanism, which can only be studied using novel analytic methods and a very advanced mass spectrometer, proves to be widespread, it will have far-reaching implications for molecular interpretation of cellular behavior.

Our Laboratory Animal Sciences and Primate Research (LASPR) Program develops and supports animal resources and facilities for biomedical research, including the identification and development of new and more appropriate animal models of human disease. The seven Regional Primate Research Centers provide specialized facilities and environments to support a broad range of biomedical research projects related to human health disorders using nonhuman primates, and serve more than 1,300 biomedical researchers in the United States. The Laboratory Animal Sciences Program supports activities related to the diagnosis and control of laboratory animal diseases, special animal colonies, animal model development, post-doctoral training programs in laboratory animal medicine, and the improvement of laboratory animal facilities at biomedical research institutions. In 1990, NCRR announced two programs for laboratory animal facilities, one targeted to small institutions receiving less than $500,000 in PHS funds, and the other for larger schools. The AIDS Animal Models Program supports breeding and breeding-associated research on chimpanzees and retrovirus/herpes-virus free colonies of rhesus monkeys for use in PHS-supported research on vaccine development and therapeutic approaches for human AIDS.

The LASPR Program has helped to produce one of the most exciting developments yet seen in the area of AIDS vaccine development. A team of investigators at the Delta Primate Center in Louisiana recently developed a prototype vaccine, made from a virus that infects rhesus monkeys, that has prevented the animals from becoming infected with simian AIDS, a disease that shares many characteristics with human AIDS. This achievement is encouraging evidence that it may be possible to develop a vaccine to protect humans from the virus that causes AIDS.

The Center's Biomedical Research Support Program, consisting of three subactivities, is designed to strengthen institutional research in the health sciences. The oldest of these subactivities, the Biomedical Research Support Grant (BRSG) formula program, has provided flexible funds on a formula basis to institutions to support biomedical research needs not served by other support programs and for purposes that could best be identified at the local level by the grantee institutions. Principal uses of BRSG funds have been support for pilot studies, interim funding for active research programs, young investigator support, and provision of central resources.

The budget request for 1991 includes $17.7 million for a significantly altered BRSG formula program. In response to changing demographics and a growing need to attract more individuals to biomedical research, one third of the program in 1991 will be focused on an effort to encourage underrepresented minorities and the economically disadvantaged to become active in the nation's research enterprise. The remaining $11.8 million will be used for the traditional BRSG formula program.

A second subactivity of the BRS program is Shared Instrumentation Grants (SIG), which are awarded to multiple investigators, each with PHS grant support, as a shared resource. Progress in medical research depends heavily upon instruments; many advances in basic and clinical research have been possible only because advances in instrumentation have opened up new, more sensitive and accurate ways to conduct scientific research. The SIG program helps institutions buy new instruments and upgrade older equipment. The program supports instruments that cost $100,000 or more, and the equipment must be shared by three or more PHS-supported investigators at an institution. The 1991 budget request continues support for this program at the 1990 level.

The Minority High School Student Research Apprentice Program (MHSSRAP), the third BRS subactivity, provides health-related research experience to minority high school students at institutions with BRSG or Minority Biomedical Research Support funding. The program is designed with the expectation that exposure to such experience will result in many of these students choosing careers in biomedical sciences. Since its beginning in 1980, the program has provided hands-on work in basic and clinical laboratories to over 8,000 apprentices, many of whom have gone on to careers in health-related fields.

The 1991 budget request for the Center includes an increase of $836 thousand for this program, which will provide the support for 1,764 apprentices.

The Biological Models and Materials Research Program was recently established in the Center to underscore the importance of providing for the development and support of nonmammalian models such as cell systems, lower organisms and nonbiological systems for biomedical research, and to provide critically important biological materials to the research community. This program received a large increase in

1990 which has allowed expansion, including the initiation of the first research project grant program for the Center in many years.

The 1991 request continues this program at approximately the 1990 level.

In December of 1989, the Center issued a request for applications for research projects on various alternatives to the use of animals in research. This represents the first time that NIH has issued such a request and demonstrates a commitment to finding and developing alternatives to using animals in research, options that can be used when appropriate instead of animals. The response to this request for applications had been encouraging, and several excellent projects are expected to be funded in 1990.

This year for the first time, the budget request for the Center includes funding for the Research Centers in Minority Institutions (RCMI) program. Although funds have previously been appropriated to the Office of the Director, the Center has always administered the program. Initiated in 1985, the RCMI program provides the resources to expand the capacity of predominantly minority, doctoral degree granting institutions to perform biomedical research, by increasing staff expertise and technical knowledge, and by upgrading scientific instrumentation. The program currently provides support to 17 institutions.

The expansion of the research capacity of RCMI grantee institutions will enable them to become full participants in biomedical research related to the infectivity of the AIDS virus and to the human genome initiative, especially as this research impacts on minority populations. The need for RCMI institutions to address the health research needs of this country has never been more urgent than now with the AIDS epidemic's disproportionate impact on minority populations. RCMI grantee institutions are located in the midst of the affected populations, and their historic role has been to address the health problems and issues that affect these populations. With respect to the human genome question, as with AIDS, there are significant and important research questions that must be addressed for minority populations. Here again, RCMI institutions are ideally located to work with minority populations. A core immunogenetics laboratory, supported by an RCMI program award, is becoming capable of genetic studies as they relate to human leukocyte antigens (HLA) phenotypes in patients with HLA-associated diseases. This RCMI program thrust will be expanded in order to participate in other human genome research.

The 1991 budget request for the Center includes an increase of $5.3 million or 30 percent for the RCMI program. The increase will allow for increased emphasis on research on ethnic-specific diseases and expanded involvement in AIDS clinical trials, and the possible funding of newly eligible institutions.

The 1991 Research Resources budget request for AIDS includes an increase of approximately five percent, which will be shared by all the programs.

The total 1991 Research Resources budget request is $319,151,000. I will be happy to answer any questions you may have.

BIOGRAPHY OF DR. ROBERT A. WHITNEY, JR.

Birthdate: July 27, 1935 - Oklahoma City, Oklahoma

Education: D.V.M., Oklahoma State University College of Veterinary Medicine, 1959; M.S. (Pharmacology), The Ohio State University, Graduate School, 1965; Resident in Laboratory Animal Medicine, The Ohio State University College of Medicine, 1965.

Professional History: 1985 to present, Director, Division of Research Services (DRS), NIH; 1988 to present, Acting Director, Division of Research Resources, NIH; 1987 to present, Director, Office of Animal Care and Use, NIH; 1984 to 1989, Chief Veterinary Officer, U.S. Public Health Service (USPHS); 1984 to present, Chairman, U.S. Government Interagency Research Animal Committee (IRAC); 1984-1985, Acting Director, DRS, NIH; 1972-1985, Chief, Veterinary Resources Branch, DRS, NIH.

Uniformed Service: 1971 to present, U.S. Public Health Service, Assistant Surgeon General (Rear Admiral, 07); 1959-1971, United States Army (Lieutenant Colonel, 05).

Societies and Associations: American Association for Laboratory Animal Science; American Association of Laboratory Animal Practitioners; American College of Laboratory Animal Medicine; American Society of Primatologists; American Veterinary Medical Association; Commissioned Officers Association, USPHS; District of Columbia Veterinary Medical Association; National Capital Area Branch, American Association for Laboratory Animal Science; The Scientific Research Society of America; Association of Military Surgeons of the United States.

Honors and Awards: USPHS Distinguished Service Medal; USPHS Surgeon General's Exemplary Service Medal; USPHS Meritorious Service Medal; USPHS Commendation Medal; Department of Army Legion of Merit; Department of Army Meritorious Service Medal; Department of Army Commendation Medal; NIH Director's Award; Ohio State University College of Veterinary Medicine, Distinguished Alumnus Award; Oklahoma State University College of Veterinary Medicine, Distinguished Graduate Recognition Award; The Charles River Prize; Alpha Zeta; Blue Key; included in 1973 Edition, American Men and Women of Science; Diplomate, American College of Laboratory Animal Medicine.

Publications: Author of one book and over 39 scientific papers.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Dr. Whitney, thank you very much for your statement. I want to return to this. I cannot figure out exactly what is being cut here. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Center for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

EXTRAMURAL ANIMAL FACILITIES

Question. I understand that less than half of the Institutions that receive NIH research grants meet animal accreditation standards. What is NIH doing to ensure the humane use of animals in research, and are you concerned that less than half of the facilities which receive NIH grants do not meet these standards?

Answer. No, we know that some institutions receiving NIH research grants involving the use of laboratory animals are not accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). The fact that they are not AAALAC-accredited does not necessarily mean that they do not meet accreditation standards, since many institutions with a completely acceptable animal care program choose not to seek official accreditation by the AAALAC.

The important point is that all institutions receiving funds from Public Health Service agencies for research projects involving the use of animals must file an assurance statement that they are in full compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) before any funds are released. The PHS Policy sets guidelines for the care and use of research animals at institutions. This includes the establishment of a properly constituted Institutional Animal Care and Use Committee (IACUC) which must review and approve all activities related to the care and use of animals, provide training for all individuals who handle animals, and inspect the animal facilities every six months. The Policy also requires institutions that are not AAALAC-accredited to describe the institution's adherence to the *Guide to the Care and Use of Laboratory Animals* (*Guide*). The *Guide* outlines the standards used by AAALAC for evaluating an institution. If an institution is not in compliance with the *Guide*, it must fully describe the deficiencies and provide a reasonable plan for correcting them.

The Office of Protection from Research Risks (OPRR) at NIH reviews all assurance statements. When major deficiencies are detected, the award may not be released until assurance is provided that the deficiencies are corrected. Therefore, all institutions which receive PHS support involving the use of laboratory animals must comply with the PHS Policy and the *Guide*, regardless of their accreditation status.

MINORITY PROGRAMS

Question. NIH has four separate programs focused on the overall objective of increasing the number of minorities engaged in biomedical research. Some of these programs are at the National Center for Research Resources and some are funded within the National Institute of General Medical Sciences. I wonder if, for the record, you would list each one of these programs and describe their purpose and their way of operating. But, could you now tell the Committee why we have four separate programs instead of one consolidated program? Wouldn't one consolidated program reduce the need for coordination, not only within the several institutes but also between the institutes?

Answer. The National Center for Research Resources (NCRR, formerly the Division of Research Resources) supports two programs targeted to minorities: (1) the Research Centers in Minority Institutions (RCMI) program, through grant support, assists predominantly minority institutions that offer the doctorate degree in the health professions or health-related sciences to improve their research infrastructure; and (2) the Minority High School Student Research Apprentice Program (MHSSRAP) provides hands-on summer research experiences to minority high school students to encourage them to consider health care professions and health research as careers.

The National Institute of General Medical Sciences (NIGMS) also supports two minority-focused programs: (1) the Minority Biomedical Research Support (MBRS) Program awards institutional grants to enable faculty and students at minority institutions to participate in biomedical research and related enrichment activities, and (2) the Minority Access to Research Careers (MARC) Program provides special research training opportunities and incentives in the biomedical sciences in order to attract and retain minority students with potential for research careers.

The NIH Task Force that recently studied the organizational location of these programs recommended that programs directed toward attracting minorities into careers in research (MARC and MBRS) be located in NIGMS, and that programs directed toward the development of research infrastructure (RCMI) be located in the NCRR. Because of its close relationship with the Biomedical Research Support Grant Program of the NCRR, the MHSSRAP will also continue to be supported by the NCRR.

Although clustering the minority programs was considered by the Task Force, it was thought to be more appropriate that the minority research and training programs should be located within the organizational component that appeared to offer the best environment for the individual program. Environment was evaluated on the basis of compatibility of each program with the overall mission of the organization and opportunities for efficient use of resources.

Coordination of minority programs within and between all the NIH organizations is an ongoing and necessary activity, since all the Institutes and Centers have some focus on minority activities within their categorical responsibilities. The NIH has recently created the position of Associate Director for Minority Affairs, which we believe will be filled within the next few months, one of whose responsibilities will be the coordination of the various minority programs of the NIH.

THIRD PARTY PAYMENT FOR CLINICAL CARE

Question. The National Center for Research Resources funds 78 clinical research centers across the country. I understand that third party payers, insurance companies, have been reluctant to provide payment coverage for individuals who are receiving medical treatment in these clinical research centers. The insurance companies have argued that it is not their role to pay for biomedical research. The other argument is made that much of the services people receive at these centers are usual and customary medical practices and that the insurance companies should at least pay for the usual and customary portion of the expense.

What is the status of this overall question and what steps are being taken to resolve it?

Answer. Since 1970, the clinical research centers have admitted some patients who require hospitalization for diagnosis or treatment according to established medical care, and who also participate in a clinical research protocol. The cost of established medical care or therapy for those patients, termed category B, is charged to the patient or a third party. The cost of special tests performed solely for research and not related to routine care is currently charged to the center grant. The third party carrier pays for those costs which relate to standard medical care and those payments are credited to the grant to offset the cost of operating the clinical research center.

There has been a progressive decline in the fraction of research patient days (category B) reimbursed to centers over the past several years by third party carriers. In the early 1980s, third party carriers began using the Health Care Financing Administration's (HCFA) regulations and interpretations as a guide to their reimbursement. Pre-admission clearance for a patient's hospitalization became a requirement. Even if a patient's projected admission was clearly indicated for medical purposes, many third party carriers denied preadmission clearance if the patient was to be admitted to a "research" center. In many cases, third party carriers retroactively denied reimbursement to hospitals for those patients who had signed a consent form to participate in a research protocol on their hospital chart - even if the patient required hospitalization for an underlying illness.

This practice of third party carriers, including Medicare and Medicaid, is currently under review by the National Committee To Review Current Procedures For Approval Of New Drugs For Cancer and AIDS. The current practice of disallowing all hospitalization costs associated with a patient receiving a potentially useful new drug or agent has had a negative impact on patients with cancer and other diseases. That practice has also had a negative effect on the scope of operation of the clinical research centers; many patients who previously participated in clinical trials for which the "usual and customary" medical costs were paid by third parties now require that all costs be paid by the clinical research center.

MINORITY HIGH SCHOOL PROGRAM

Question. The Minority High School Student Research Apprentice Program provides health-related research experience to minority high school students at institutions with Biomedical Research Support Program or Minority Biomedical Research Support funding. This is designed with the expectation that these students will choose a career in the biomedical sciences. Do you have any means of measuring the goal of this program or, in other words, can you monitor whether or not these students actually pursue careers in the biomedical sciences?

Answer. The Minority High School Student Research Apprentice Program has been in existence since 1980, when it began with 200 students participating. Through 1989 over 8,000 apprentices have been supported. From data provided by the participating institutions and the apprentices, we can report the following positive outcomes:

- 54% report that the program helped to develop an interest in a research career.
- 87% expressed a career choice in biological or health professional sciences.
- Many of the students have been awarded prizes in local science fairs.
- Of the 40 Westinghouse Science Talent Search winners in 1988, three were Minority High School Student Research Apprentices the previous summer.
- Some early returns on a poll of the original 45 schools in the program in 1980 show that most students have gone on to college, many have continued in graduate or a health professional school and some have gone on to receive M.D. degrees.

SHARED INSTRUMENTATION PROGRAM

Question. Institutions which receive Biomedical Research Support Grant funds are also eligible to apply for assistance under the Shared Instrument Grants program. These grants provide a mechanism to acquire state-of-the-art instrumentation costing between $100,000 and $400,000. The budget request included $31.8 million for continuation of this program in FY91. How much money was actually awarded for this program last year? What percentage of grant applications were you able to fund in FY90 and could you tell us what this program would cost if you were able to cover the cost of all shared instrument grant requests?

Answer. In FY 1990, $32,593,000 (including $765,000 for AIDS) was appropriated for the Shared Instrumentation Grant (SIG) program. We received 403 applications for the SIG program in FY 1990 compared to 407 in FY 1989, and we estimate that we will be able to make 140 awards, 10 less than in FY 1989. Although we had a slight increase in the budget, the average direct costs recommended for funding increased from $213,000 to $230,000. Consequently, our award rate in FY 1990 will decrease to approximately 36 percent compared to 45 percent in FY 1989. In FY 1990, the total amount required to cover the cost of all approved shared instrumentation requests would be $84.6 million.

BIOMEDICAL RESEARCH TECHNOLOGY

Question. We are beginning to hear in the news more and more about the possibilities brought to research by new technologies such as synchrotron radiation and nuclear magnetic resonance. Tell us what NCRR is doing to advance use of these technologies by biomedical researchers.

Answer. The NCRR has traditionally been the unit of the NIH which has invested in the development of new research technologies for the biomedical community. These technologies are made available through regional and national resource centers, including facilities for synchrotron radiation and nuclear magnetic resonance. The technologies become available to biomedical researchers around the country through the collaborative, service and training mechanisms of the NCRR centers.

Question. Can you support any of these with your 1991 request?

Answer. The NCRR presently supports 59 resource centers including 4 resources in synchrotron radiation and a number of projects in nuclear magnetic resonance both for biochemical spectroscopy and whole body imaging and spectroscopy. Other areas represented are resources for computer applications to a wide variety of biomedical problems, mass spectrometry, high and intermediate voltage electron microscopy, and a variety of biophysical tools such as fluorescence and calorimetry. The current program can be maintained with the requested 1991 budget provided there are negotiated reductions in the approved budgets for these projects.

Question. In your professional judgment what is needed to take advantage of the most pressing needs of researchers and advances in physical and engineering sciences?

Answer. Opportunities have never been better for application of advances in the physical and engineering sciences to biomedical research. The emerging technologies offer unprecedented power--both in speed and in resolution of microscopic fine structure--for studying biological systems. These technologies are increasingly expensive, more so than the technologies with which NCRR has customarily dealt. An increase of at least $15 million in the annual NCRR budget would be needed to set up and equip shared resources in identified new technologies over the periods 1991-1995, and an additional $5 million annually in operating costs would be needed starting in 1992.

Question. Also, how is this program related to the Shared Instrument Grant Program?

Answer. The Shared Instrument Grant Program, a component of the Biomedical Research Support Program, provides support to institutions for their procurement of expensive instruments which are currently available to researchers through commercial vendors. In other words, the Shared Instrument Grant Program now provides the kinds of instrumentation that was developed in part by the Biomedical Research Technology Program several years ago.

AIDS RESEARCH

Question. We understand that the resources developed and supported by the National Center for Research Resources provide the infrastructure so that research supported by the institutes can proceed. Give us an example of a particularly important advance in AIDS research which was made possible by one of the NCRR resources.

Answer. A variety of retroviruses which cause AIDS-like disease in nonhuman primates are under intense study at the Delta and New England Regional Primate Research Centers. Investigations at both of these Centers have demonstrated that immunization with a killed Simian Immunodeficiency Virus (SIV) vaccine prevented infection and disease in rhesus monkeys which had been experimentally exposed to the infectious SIV. All non-immunized (control) animals exposed to the same virus became infected and developed SAIDS and most animals have died. These successful vaccine development studies with SIV (which is very similar to human immunodeficiency virus (HIV) provide proof and new hope that a vaccine for human AIDS is possible and can be successfully developed within the next several years.

COST OF USDA ANIMAL CARE REGULATIONS

Question. In 1985 Congress enacted legislation (Food Security Act) that required promulgation of a set of new regulations governing the care, use and treatment of laboratory animals. Originally it was estimated that it would cost research facilities over $1 billion to upgrade their lab facilities to be in basic compliance with the new regulations. How are NIH supported facilities (grantees) going to pay for these cost increases?

Answer. Biomedical institutions will undoubtedly have a difficult time finding the large amounts of funds which will be required to comply with new regulations (currently being developed) governing the care, use, and treatment of laboratory animals for the implementation of legislation contained in the Food Security Act of 1985. Some of the large institutions may be able to use endowment funds or seek state support for this purpose. However, sources of that nature will not be available to many institutions. Consequently, it is believed that many institutions will not be able to comply with the new regulations and may discontinue biomedical research involving animals. As a result, the nation's overall biomedical research efforts and productivity could be greatly diminished. It could also limit opportunities for exposure of students to biomedical research at a time when the number of new biomedical investigators is on a decline.

Question. Can you tell us whether or not the grant requests you are receiving now have been increased in order to cover these costs?

Answer. No significant increases have been reported to date in budgets of grant applications for costs of complying with the new regulations. Such increases may occur after Part III of the regulations is finalized and fully implemented by the USDA. Per diem rates for animal maintenance and care may have to be increased significantly to cover the higher costs. Increases in indirect cost rates (to cover increased administrative costs to the institutions) can also be anticipated.

Question. Is it fair to say that most, if not all, of the costs incurred with enactment of the 1985 law will be passed on eventually to taxpayers in the form of higher cost grant requests?

Answer. Most of the costs incurred due to enactment of the 1985 law will eventually be passed on to the American taxpayer because of higher budget requests in grant and contract applications submitted to federal and state funding agencies. Academic institutions may be forced to raise tuition rates; hospitals may increase their charges for patient care; and private industry, e.g., pharmaceutical companies may increase the price of drugs and biologics to offset increased costs of research and testing involving the use of laboratory animals.

BIOMEDICAL RESEARCH TECHNOLOGY

Question. The committee has heard much about the Biomedical Research Technology centers which the National Center for Research Resources supports. How does the Center develop these technologies in the first place?

Answer. The resource Centers are investigator-initiated activities that are peer reviewed for scientific merit prior to funding by NCRR. Following successful review and assurance of the need for the technology, a new facility is approved for funding by NCRR for the entire research and development effort. In some cases, the basic science and engineering components have been supported by industry or by other government agencies (Department of Energy, National Science Foundation, Department of Defense) as part of, for example, national efforts in high energy physics, NCRR may also support the development of biomedical applications of the new technology.

Question. How is this activity related to your small grants, resource-related research projects, or Small Business Innovative Research grants?

Answer. The small grants program supports pilot studies in high risk innovative areas of technology and engineering to demonstrate the feasibility of new approaches. These grants are available to both academic and commercial sector applicants. The resource related research projects provide support for development of promising novel technologies in order to prepare them to be available in a resource center. The SBIR program supports the development of technologies by small business applicants. Successful SBIR applicants have previously received support through the small grants program. NCRR programs have been successful in transferring new technologies to the commercial sector.

Question. Finally, how do you continue development of the technology once a center is established?

Answer. All BRTP resource centers are required to have technology research and development as an essential component of their resource. Successful technologies that become readily available and do not need further development for application to biomedical research problems are no longer supported by this mechanism.

BIOMEDICAL RESEARCH SUPPORT GRANTS

Question. In 1991 the President has proposed a much reduced Biomedical Research Support Grant with a new twist--a focus on underrepresented minorities and disadvantaged persons. Why are you proposing the reduction and this particular focus? What effect will such targeting have on the recipients of the BRSG funds?

Answer. The Administration has set a high priority on addressing the need to attract more young people to careers in science and engineering. In particular, we know that the changing demographics in the United States will yield many more members of minority groups and women entering the job market by the turn of the century. We believe it is very important to attract as many of these people as possible to explore careers in biomedical research and the health professions. Therefore, a portion of this Program will be used by the local institutions to address this need.

We recognize that this new focus will cause a reduction in the amount of funds available under the traditional program, support of young investigators, interim support for funded investigators, pilot research, and development of centralized resources.

However difficult the choice, we believe that our priorities are set correctly, in light of the need to encourage more minority participation in health research.

REGIONAL PRIMATE RESEARCH CENTERS

Question. Last year directors of the Regional Primate Research Centers testified that core support in the centers has been decreasing over the past years. Is this true? If it is true what is the real effect on the ability of the Primate Research Centers to continue their programs of research? In your professional judgment, what is needed to correct the situation?

Answer. It is true that core support has not been increased in the 1991 request. It is also true that inflationary increases in institutional salaries and other areas are decreasing the Centers' capacity to maintain the core support that is required to accommodate both the non-AIDS Center operations and the increasing number of AIDS research projects, and to maintain the number of animals needed for these many research projects. In my professional judgement, an additional $3 million in 1991 would correct the situation in the near term to provide sufficient funding to keep the Centers operating. However, funding fully at the level of the National Advisory Research Resources Council recommendations would require an additional $9 million, and could, if continued, provide a longer term solution to this problem.

EXTRAMURAL CONSTRUCTION AUTHORITY

Question. We know that our colleagues have been considering various authorizations of construction authority for NIH and specifically for the National Center for Research Resources. Could you comment on what you know to be the needs for such authority at this time.

Answer. Several studies have been completed on the need for construction in the academic and research community. Of particular interest to the NCRR are the conditions faced by the Regional Primate Research Centers.

We are mindful that construction authority could be useful as well in addressing other needs for facilities in which to conduct AIDS research. In 1988 and 1989 the funds were appropriated to NCRR for the Research Facility Improvement Program. While we funded 50 of the requests, another 65 remain approved but unfunded.

Other needs within NCRR programs include the Animal Facility Improvement Program wherein renovations are undertaken to assist institutions to comply with the Animal Welfare Act and the Public Health Service policy on the care and use of animals in research. While not all needs require construction, some needs which are met by renovation might be more economically addressed through new construction, and some cannot be met by renovation at all.

Similar needs for construction activities occur throughout the PHS extramural program in centers and facilities where research supported by the several institutes and centers is conducted.

RESEARCH FACILITIES IMPROVEMENT

Question. In 1988 and 1989 NCRR received funds to support the Research Facilities Improvement Program. No funds were requested in 1990 and no funds have been requested in 1991. Does this mean that this program is no longer needed?

Answer. No, this does not mean that the program is no longer needed. It simply indicates that other NIH programs had a higher priority than this program.

Of the 115 applications received, 50 awards were made. We believe that, had funds been available for additional solicitations, many more meritorious applications would have been received.

MINORITY HIGH SCHOOL PROGRAM

Question. The Minority High School's Summer Research Apprentice Program has supported students since the early 1980s. How are these apprentices involved in research? Please describe your plans for this program in 1991.

Answer. Through 1989 over 8,000 minority high school students have been supported through this important program whose mission is to attract students to potential careers in biomedical research and health professions. In 1990, we will provide support to some 1,206 minority high school students. Moreover, several other institutes and centers at NIH have agreed to provide additional funding for this program. In 1991 we anticipate being able to support 1,764 high school students with the funds requested for this program. Together with funds made available through the BRSG program, the FY 1991 budget request would allow 5,100 high school students as well as some of their teachers to participate in the program.

PRIMATE BREEDING AND RESEARCH

Question. We are aware that the National Center for Research Resources continues its chimpanzee breeding and research program. The program's goal is to assure the availability of chimpanzees for research in this country. In addition, it is our understanding that the Center is supporting the development of a colony of specific pathogen free rhesus monkeys for research in AIDS research. Please give us a status report of these two programs. What are you doing to assure that these animals are raised, cared for, and used in the best possible circumstances? Chimpanzees have been declared as an endangered species. How can you justify using those animals for research?

Answer.

A. Chimpanzee Breeding and Research Program - This program was established in September 1986 to create self-sustaining breeding colonies and provide support for research efforts to help preserve this species. This nationwide program was designed to bring the expertise of chimpanzee breeders and researchers together in a unified effort. There are currently 431 disease-free breeding chimpanzees in the program's five colonies. The breeding efforts have been very successful, with a total of 147 live births produced during the first three years of this program.

B. Specific-Pathogen-Free (SPF) Rhesus Monkey Breeding and Research Program

This program was initiated in September 1988 to create self-sustaining rhesus breeding colonies which are free from infection with simian retroviruses and herpes B virus. This is the first national effort to ensure the development of a stable population of SPF rhesus monkeys. There are six breeding colonies and two research projects (behavior and genetics) in this total effort. The program is progressing well and will provide a dependable supply of high quality SPF rhesus monkeys for AIDS-related research and testing.

A national management committee for the Chimpanzee Breeding and Research Program includes representatives of the participating institutions as well as an ethicist and zoological park director. The management committee is responsible for developing standards to be followed by each participating institution and addressing questions of concern to the participants, the public and the government. Thus far, no chimpanzees have been issued for use in research.

Only chimpanzees in the wild are considered endangered. Those bred and raised in captivity in the United States are not considered endangered, and the breeding program is actually contributing to the population of chimpanzees, since half of the animals produced will be returned to the breeding resources.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

ALTERNATIVES RESEARCH

Question. Dr. Whitney, as you know, the Committee strongly supports the exploration and development of alternatives to the use of animals in biomedical research and urged the NCRR to expand its support for alternatives research. What action has the NCRR taken in response to the Committee's direction?

Answer. The NCRR established the Biological Models and Materials Research Program in the fall of 1989 to give greater visibility and priority to the development and provision of alternatives to the use of animals in research where such alternatives are appropriate. In response to the directive of the Appropriations Conference Committee, the budget for this program was increased by approximately 44 percent in FY 1990, from $3,727,000 to $5,364,000. As part of the effort to encourage the development of nonmammalian model systems for use in research, the NCRR issued a Request for Applications in December of 1989, and we expect to fund 4 to 6 research project grants in 1990 in this area.

Question. Does the budget for FY '91 include additional funds to expand support for alternatives research? How many research grants does the NCRR expect to fund in FY '91? How does that compare with FY '89 and FY '90?

Answer. The budget request for FY 1991 for this program is approximately the same as the FY 1990 appropriation. The NCRR expects to fund the continuation costs of the 4 to 6 new grants initiated in FY 1990. In FY 1989 the NCRR funded no research project grants.

PARTICIPATION OF MINORITIES IN RESEARCH

Question. Dr. Whitney, minorities and women continue to be underrepresented in the field of biomedical research. With a third of those entering the workforce projected to be minorities by the turn of the century, what has the NCRR done to encourage participation of minorities in biomedical research?

Answer. The NCRR supports two programs that encourage the participation of minorities in research: (1) the Research Centers in Minority Institutions (RCMI) program assists predominantly minority institutions that offer the doctorate degree in the health professions or health-related sciences to improve their research infrastructure, and (2) the Minority High School Student Research Apprentice Program (MHSSRAP) provides hands-on summer research experiences to minority high school students to encourage them to consider health care professions and health research as careers. Both of these programs are high priorities of the NCRR.

In FY 1991, the NCRR will initiate a new program in the General Clinical Research Centers, designed to support clinical research training for minority physicians and dentists as Clinical Associate Physicians.

Question. How much support was provided for these activities in 1990? How much is requested for fiscal year 1991?

Answer. In FY 1990, $17,503,000 was appropriated for the RCMI Program; in FY 1991, the NCRR has requested $22,833,000 for this program, an increase of 30 percent.

In the MHSSRAP, the FY 1990 appropriation for the NCRR included $1,810,000. In addition, approximately $1.4 million more was provided by the NIH Institutes and Centers (including NCRR) and the National Institute of Mental Health to bring this program to a level of $3.2 million. In FY 1991, the NCRR has requested $2,646,000 for the MHSSRAP, and will shift $5.9 million earmarked for encouragement of minority participation in biomedical research from the Biomedical Research Support Grant formula program to the MHSSRAP. This will provide for a total funding level of $8.5 million in FY 1991, and will include approximately $850,000 to initiate a pilot training program for high school science teachers, particularly those in high schools serving minority populations.

The new Clinical Associate Program for minority physicians and dentists will be supported at a level of approximately $450,000 in FY 1991. No increase has been requested for this program; it will be supported within the levels available to the General Clinical Research Centers.

NATIONAL CENTER FOR NURSING RESEARCH

STATEMENT OF DR. ADA SUE HINSHAW, DIRECTOR

SUMMARY STATEMENT

Senator **HARKIN**. National Center for Nursing Research, Dr. Hinshaw? I am glad to have you with us this afternoon. I look forward to hearing the overall status and health of the nursing profession in America today.

Your Center is requesting $35.127 million for next year, for a 4.82-percent increase. Please proceed.

Dr. **HINSHAW**. Thank you, Senator Harkin. It is an honor to appear before you again to discuss the programs of the National Center for Nursing Research and several important scientific opportunities that will provide information for guiding nursing practice.

The National Center has made considerable advances in the past year: first, the award of the first four research center grants; second, the establishment of a new collaborative intramural research program; third, the completion of the second step of the research training initiative; fourth, release of the reports of the first two priority expert panels for the National Nursing Research Agenda on the nursing research needed for low birth weight infants and on patients with HIV infection; the development of research initiatives for these two areas; the development of a rural health initiative; and finally, the establishment of a new program of research in bioethics and clinical practice.

The initiative which we have begun in research on the prevention and care of low birth weight infants has several major foci: strategies for preventing low birth weight infants through prenatal care; care of the infant in the neonatal intensive care nursery; and followup care of the infant and mother after discharge.

A major health challenge facing our Nation of course is the AIDS epidemic, and the Center is strongly committed to research on the physical, psychosocial and ethical problems central to the prevention of HIV infection and the care of individuals with AIDS, their partners and their families. Our newly established intramural research program will begin in March with research in this field.

The increasing age profile of the Nation is focusing growing attention on Alzheimer's disease and other dementias, frailty, and injuries among older persons.

The NCNR is defining and prioritizing nursing issues primarily dealing with the broader problems of family caregiving and the difficulties facing both formal and informal caregivers in this particular field. We also have begun a research initiative with the NIA to prevent falls in the frail elderly.

PREPARED STATEMENT

Finally, we are very interested and concerned, given the opportunity from the Senate Appropriations Committee in last year's appropriation language, to be able now to begin an initiative in health care in rural areas, and are working with several other public health agencies to develop a research and demonstration initiative to address the health issues of rural Americans with a special focus on minorities and native Americans.

Mr. Chairman, the fiscal year 1991 budget request for the Center is $35,127,000. I would be pleased to answer any questions that you may have.

[The statement follows:]

STATEMENT OF DR. ADA SUE HINSHAW

Mr. Chairman, I am honored to appear before you again to discuss the programs of the National Center for Nursing Research, the current state of knowledge for nursing practice, and the challenges facing us in patient care and the promotion of health in this country.

The National Center has made considerable advances in the past year: the award of the first four research center grants; establishment of a new collaborative intramural research program; completion of the second step of the research training initiative; completion of the reports of the first two priority expert panels for the National Nursing Research Agenda -- on the nursing research needed for low birthweight infants and on patients with HIV infection; development of research initiatives for those two areas; development of a rural health initiative; and the establishment of a new program of research in bioethics and clinical practice.

Since prevention of and the care of low birthweight infants is a major area of scientific challenge and potential for nursing research, a major initiative has begun. This research has four major foci: preconception health, prenatal care, care of the infant in the hospital, and follow-up care of the infant and mother after discharge.

One NCNR-supported scientist is testing the effectiveness of prenatal and post partum nurse home visitation services as a means of enhancing the health and well-being of unwed poor women and their first-born children. Visiting nurses will teach the young mothers to improve their diets, to identify complications in pregnancy, and to care for their babies, including cognitive skill development and emotional development. The nurses will also encourage the mothers to return to school and find employment after the birth. For the mothers, the study will measure changes in prenatal health habits, infant caregiving skills, and other behaviors and skills. For the children, the study will measure the occurrence of prematurity and low birthweight, several types of growth and nutritional problems, and instances of child abuse and neglect. The preliminary study showed positive outcomes from the nurse home-visitation services.

Methods of caring for low birthweight infants in neonatal intensive care nurseries are another priority area for the NCNR. Physical care of these infants such as feeding, respiratory care, skin care, and positioning needs further study, to identify optimal care practices during hospitalization and after discharge. In December 1989 NCNR issued a program announcement, in collaboration with the National Institute of Child Health and Human Development, inviting applications to address these issues.

The most ominous health challenge facing our Nation is of course the AIDS epidemic. NCNR is strongly committed to research on the physical, psychosocial, and ethical problems central to prevention of HIV infection and the care of persons with AIDS, their partners and families. We are especially pleased with the establishment in 1990 of our new Intramural Research Program in this field, in collaboration with the National Institute for Allergy and Infectious Diseases and the NIH Clinical Center.

NCNR intramural investigators will conduct basic and clinical research in symptom management of AIDS patients, seeking to minimize the harmful effects of the infection and treatments, such as unintentional weight loss, diarrhea, fatigue, oral complications, dementia, anxiety, pain, and depression. For example, as NIAID clinicians treat asymptomatic HIV-infected persons with AZT or alpha interferon, NCNR nurse scientists will quantify changes in nutritional status, and then develop nursing interventions to minimize nutritional problems such as anorexia, nausea, and weight loss. As long as HIV infection remains incurable and advanced treatments allow individuals to live longer, it is important to discover ways to decrease morbidity, to diminish the economic and personal costs of infection and treatment, and to promote an optimal quality of life.

An NCNR extramural investigator is studying health characteristics of infants of high risk mothers who remain HIV antibody positive over a three year period, as compared with infants who show no HIV antibody or who seroconvert from positive to negative. Many of the high risk mothers decline to be tested for antibodies to the virus but permit testing of their infants. However, HIV antibody testing of newborns is not reliable. Some infants who test positive later convert from seropositive to seronegative, and develop no symptoms associated with HIV infection. They may have had only transient maternal antibody and may be free of the virus. Developing better methods of detecting which children are actually infected is crucial to offering earlier, more effective care. Physiological and psychosocial growth and development measures as well as biological indices of HIV seroconversion are being tested, and may prove useful to nurses caring for high risk infants in the future.

The increasing age profile of the nation has focused growing attention on Alzheimer's Disease and other dementias, frailty and injuries among older persons, and the broader problems of family caregiving. The Center is defining and prioritizing nursing issues related to formal and informal caregiving practices. The Center has issued both a research training program announcement and a research support program announcement relevant to Alzheimer's Disease and related disorders, reducing frailty in the elderly, and issues in caregiving. One of the NCNR's new research centers focuses on related patient care issues with the elderly, for example, assessment of activities of daily living in determining the risk of falling in the elderly.

Some data suggest that informal caregivers (relatives, friends, or others who are not paid) experience extensive physical, emotional, and financial costs related to caregiving. One project focuses on refinement and testing of a model of caregiver perceptions of the burden and measures of the quality of caregiving. This study will assess changes in these relationships over time, to indicate points at which interventions by nurses may be most effective. This model should enable nurses to assist families in increasing the quality of care and identifying coping strategies.

The new Exploratory Center for Nursing Research at the University of Minnesota specializes in long term care of the elderly, particularly factors which influence the autonomy and independent functioning of older persons. Studies include clinical nursing interventions for aggressive behavior by cognitively impaired older people in nursing homes, prevention of falls among hospitalized elders, assessment of the needs of older persons after hospital discharge, and the mix of formal and informal caregiving services best for the home.

Behavioral research related to health is a key part of the mandate of the National Center for Nursing Research, and accounted for over one third of Center-supported research in 1989. Our research addresses the behavior of patients and care providers related to health and illness. Our new Specialized Center for Nursing Research at the University of Pennsylvania emphasizes advancing care in serious illness, including behavioral research efforts. One study characterizes depressive signs and symptoms experienced by stroke patients at three points in time after occurrence of the stroke. The location of the stroke within the brain will be related to the depressive symptoms observed. The results of this research should give nurses caring for stroke patients a tool for detecting depression, in order to make timely referrals for treatment.

We are especially interested in the development and maintenance of health promoting behaviors and the measurement of positive outcomes correlated to those behaviors. One of our grantees is studying the validity of the Health Promotion Model for explaining health promoting behaviors in adult populations of various ages with or without a recent catastrophic illness. The issues to be studied include exercise adherence among working adults, exercise adherence after myocardial infarction, ambulatory cancer patients' health promoting behaviors, and health promoting behaviors among older adults.

The adequacy of health care in rural areas is a growing challenge to the Nation. NCNR is working with other PHS agencies to develop a research and demonstration initiative that will address health issues of rural Americans, with a focus on the special needs of American Indians, native Alaskans and native Hawaiians, native Samoans, and other Pacific basin populations. Access to nursing services for rural populations is critical at this time.

NCNR is funding a study of home care, continuity of care and community support for older adults in two rural areas of Colorado. The investigator is describing the types and patterns of professional, family and community home health care services, the continuity of care from hospital discharge through home care, and problems with the services. It is expected that a comprehensive understanding of rural home care will provide a foundation for improved health care services to the rural elderly.

NCNR will be collaborating with the Agency for Health Care Policy and Research on the newly mandated Medical Treatment Effectiveness Program. The NCNR has emphasized the importance of quality of care and patient outcomes in its clinical research programs.

As a relatively new arm of the NIH, the NCNR must produce high-quality young investigators for an expanding area of science. Emphasis has been placed on increasing the number of trainees, building postdoctoral programs, and encouraging more minority nurse scientists. In 1989, the Center supported 228 research trainees and research career awards, thereby exceeding the second annual goal of our training initiative. The third goal of 270 for 1990 has been adjusted to 257.

The NCNR has implemented an initiative providing special research opportunities for minority faculty and students. The Center has funded positions for minority trainees on existing institutional training grants as well as special supplements for research assistants on research project grants. The new specialized centers have been required to incorporate minority outreach into their research efforts. An ad hoc task force advises the NCNR on strategies for facilitating research training for minority nurses.

As the base of knowledge for nursing expands, we are confident that health care will become better understood and more effective, and the quality of life for millions of Americans who receive care each year will be enhanced by the extensive research initiatives planned and conducted by the NCNR.

Mr. Chairman, the FY 1991 budget request for this Center is $35,127,000. I will be pleased to answer any questions that you may have.

BIOGRAPHY OF DR. ADA SUE HINSHAW

May 20, 1939. Arkansas City, Kansas. Divorced, two children.

Education:

B.S., University of Kansas, Lawrence, Kansas, 1961;
M.S.N., Yale University, New Haven, Connecticut, 1963;
M.A., University of Arizona, Tucson, Arizona, 1973;
Ph.D., University of Arizona, Tucson, Arizona, 1975.

Professional History: 1963-1965, Instructor and Chairperson, Maternity Nursing Section, University of Kansas, Lawrence, Kansas. 1966-1967, Assistant Professor, School of Nursing, University of California, San Francisco, California. 1968-1971, Administrative Coordinator, First Year Undergraduate Program, School of Nursing, University of California, San Francisco, California. 1971-1975, Masters' and doctoral studies, University of Arizona, Tucson, Arizona. 1975-1987, Liaison Position: Director of Nursing Research, University Medical Center, Tucson, Arizona and Professor and Director of Research, College of Nursing, University of Arizona, Tucson, Arizona. 1987-Present, Director, National Center for Nursing Research, National Institutes of Health.

Professional Organizations: American Academy of Nursing, American Nurses' Association (ANA), ANA Council of Nurse Researchers, Arizona Nurses' Association, Sigma Xi, Western Society for

Research in Nursing, Sigma Theta Tau, National Academies of Practice, Institute of Medicine

Honors, Awards: Kay Schilter Award, University of Kansas School of Nursing, 1961. Lucille Petry Leone Award, National League for Nursing, 1971. Wolanin Geriatric Nursing Research Award, University of Arizona College of Nursing, 1978. Sigma Theta Tau, Beta Mu Chapter, Award for Excellence in Nursing Education, 1980. Alumni of the Year Award, University of Kansas School of Nursing, 1981. Distinguished Alumni Award, Yale University School of Nursing, 1981. Nurse Scientist of the Year Award, American Nurses' Association, 1985. Elizabeth McWilliams Miller Award for Excellence in Research, Sigma Theta Tau International, 1987. Doctor of Science Degree, University of Maryland, 1988. Doctor of Science Degree, Medical College of Ohio, 1988.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. Dr. Hinshaw, thank you very much. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Center for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

COMMISSION ON NURSING

Question. Last year in our Conference Report, we asked that the National Center for Nursing Research to provide funds for one year continuation of the Commission on Nursing. This additional year would be used to implement the findings of the Commission report issued last year. What is the status of extending the life of the Commission for one additional year?

Answer. A Charter to re-establish the Commission on Nursing was recently signed by the Secretary for Health and Human Services. The Commission will exist for one year from the inception of the Charter. Currently, the Commission is housed with Dr. O. Marie Henry, Assistant Surgeon General, Chief Nurse, PHS Commissioned Corps, and Director, Division of Nursing, Health Resources and Services Administration. Since the mandate to attend to nursing shortage issues from a manpower and education perspective resides with the Division of Nursing, the responsibility for the Commission and the $272,000 appropriated to NCNR for the support of the Commission were transferred to the Division early in FY 1990.

Question. Dr. Hinshaw, could you outline, for the Committee, those several recommendations of the Commission on Nursing which will be the agenda for the newly, soon to be reconstituted, Commission on Nursing?

Answer. The recently chartered Commission on Nursing is to focus on the implementation of the recommendations of the original 1987 Commission. The initial plans for the new Commission focused on several broad areas flowing from the 1987 recommendations; recruitment and the educational pathways, retention and career development, restructuring nursing services and effective utilization of nursing personnel, information systems and related technology in nursing, and data collection and analysis requirements for long term evaluation of the nursing shortage and the success of the implementation strategies.

RURAL NURSES

Question. I understand that studies and surveys have found that the stress level for nurses working in rural areas is much greater than for nurses in urban areas largely because they are called upon to provide a much broader array of services. Do you believe that this special circumstance would warrant a sub-specialty in nursing and warrants special research focused on the problems of rural nurses?

Answer. There is a need for clinical experiences within educational programs in rural areas. The Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration (HRSA), supports several projects that target issues in providing educational opportunities for rural nurses.

The NCNR, in collaboration with the Division of Nursing, HRSA, is supporting a cooperative agreement with two institutions and several sites for research and demonstrations that will document models of nursing care to improve nurse retention and patient outcomes in acute care settings that include rural hospitals. NCNR continues to support research that addresses cost-effectiveness methods for improving patient care outcomes, utilizing nurses, nurse support staff and other professionals in rural areas.

RURAL HEALTH RESEARCH

Question. Last year the Committee urged the Center to enhance its efforts in rural health care. Describe the Nursing Center's research in rural areas.

Answer. The NCNR is currently funding studies through an intraagency agreement with the Division of Nursing that are testing innovative practice models for nurses in acute care hospitals. The projects include rural hospitals and are expected to provide valuable information on the practice issues for nurses in rural areas. For example, it is widely believed that nurses in rural areas are called upon to provide a broader array of services and perform under more severe staffing shortages. The studies will investigate several approaches to address shaping practice environments, such as hospital units, to increase nurse retention and link nursing resources to measures of quality of care.

The Senate Report language recommended proposals that target "epidemiological studies, clinical intervention studies (particularly those related to the elderly, infants, children, adolescents, and childbearing women), health promotion studies focused on chronic illness and other rural health problems, and studies of nursing care delivery..." In response to these directions, the NCNR is or will be funding the following studies: an intervention study that will test approaches to reducing risks for cardiovascular disease in school-age children in rural North Carolina, an epidemiological study of Multiple Sclerosis in rural populations, and a study of home care for older adults in a rural area of Colorado.

The National Center for Nursing Research has been collaborating with the Division of Nursing of the Health Resources and Services Administration and the newly established Agency for Health Care Policy and Research in the development of an initiative that will focus on improving the health of minority persons living in rural areas. This work has recently culminated in a joint decision to support research and demonstration projects that will study the implementation of replicable community-based nursing practice models for providing health care to minority persons living in rural areas. This effort is titled "Research Demonstration on Community-Based Rural Health Care Models for Minority Populations." A request for applications that will communicate our agencies' interest in receiving grant applications in this area will be published in the NIH Guide to Grants and Contracts on March 9, 1990. It is anticipated that two or three applications will be funded in FY 1990.

LOW BIRTHWEIGHT INFANTS

Question. I understand that one of your research priority areas is the prevention and care of low birthweight babies. This, of course, is particularly important in our efforts to reduce the infant mortality rate. What is the status of research in this area and what are we learning from the Nursing Center's research in this area?

Answer. The research on low birthweight infants focuses on two primary areas: the prevention of low birthweight through the prevention of premature labor and of intrauterine growth retardation, and the care of the low birthweight infant after delivery. This research is conducted by teams of nurse scientists together with members of other disciplines. From this research we are learning more about women's behaviors and factors related to the risk of low birthweight infants such as smoking, alcohol, substance abuse, and stress. The Center has approved for funding an interdisciplinary study of a minority population at risk for premature labor. The scientists will examine nursing interventions of frequent contacts and support to reduce the incidence of premature labor.

Through our current research we are beginning to know more about the etiology of premature labor and intrauterine growth retardation. As we learn more about the factors affecting low birthweight infants there is increasing need for multifactorial, interdisciplinary studies to examine the interaction of the biomolecular, physiological, behavioral, and system factors affecting the prevention of low birthweight. A significant area for research is intervention studies for the prevention of pregnancies in adolescents, and studies to support changes in maternal behaviors to prevent premature labor and intrauterine growth retardation.

We are learning the significance of care procedures in neonatal intensive care units on low birthweight infants, and that the infant's responses to care is influenced by the behavior and organizational state of the infant. Clinical trials to test further the care procedures and the responses of the infant are necessary to reduce the morbidity of the infants. We know from nursing research that low birthweight infants may have ongoing problems including some behavioral or learning problems not apparent until the child enters school. We need to continue to follow these children over time and to study the interventions needed through early childhood. Another study showed that follow-up of very low birthweight infants and their mothers by a master's prepared nurse can result in earlier and safe discharge of the infant. Further studies of this type of intervention with longer follow-up of the infants are necessary.

INNOVATIVE PRACTICE MODELS

Question. One of the points that was well learned from the study of the causes of the nursing shortage was the dissatisfaction of nurses with the content of their jobs. Bluntly put, nurses were not being given the opportunity to fully use their professional training and were often not listened to as a member of the health care team. As a response, I understand that the Nursing Center has developed so-called innovative practice models, or recommended job structure and content for nurses, and in fact the implementation of these innovative practice models may well affect patient outcomes.

What can you tell us about the success you are having in encouraging the use of these innovative practice models and what evidence is there that the implementation of these models could in fact affect the outcome of patients?

Answer. The recent activities carried out by both public and private sector organizations to examine the shortage of nurses helped to provide evidence that the factors influencing their availability was more complex than anticipated, and would require responses from all levels of the health care system. The timing of the current shortage corresponded with a decline in enrollments in schools of nursing across the country. Recognition that the enrollment changes could compound the shortage in the future increased concern that the quality of patient care in the settings and communities where nurses practice, particularly rural and other underserved areas, would be seriously and deeply compromised. Understanding how to protect patient care and assure the appropriate utilization of nurses became the aim of the activities of nurse researchers, clinicians and managers.

The National Center for Nursing Research (NCNR), in conjunction with the Division of Nursing, HRSA, examined the relationship between the availability and allocation of nursing resources and their impact on the delivery of quality patient care. The proceedings of this conference, titled "State of the Science Invitational Conference: Nursing Resources and the Delivery of Patient Care," were published in November 1988. In addition, NCNR staff worked with the DHHS Secretary's Commission on Nursing (SCN) to investigate the factors influencing the national shortage of registered nurses. The SCN Interim Report published in July 1988 indicated that the current shortage, while demand driven, was also a reflection of nurses discontent with their perceived inability to practice nursing in a manner appropriate to the standards of the profession. These findings corresponded to findings of earlier studies that examined factors related to turnover and retention of nurses in various health care settings.

Only a small number of studies have reported on the influence of nurses on patient outcomes. From these studies there is evidence that clinical collaboration between physicians and nurses influences the outcomes of care in intensive care units, that a higher proportion of registered nurses providing care in hospitals lowers patient mortality, and that the care in free-standing community-based Birth Centers, where care is predominately provided by nurse midwives, is safe and has a lower cesarean section rate than hospital care provided to low-risk pregnant women.

The position of NCNR has been that there is evidence that the quality of patient care is influenced by the clinical practice of nurses. The findings from several studies identify factors that stimulate nurse satisfaction with employment in clinical practice settings, increase retention and decrease turnover. Finding how best to configure the clinical practice settings so that high quality patient care is given and highly competent nurses are retained and professionally flourish requires considerable study which has only recently begun.

With this information as background, NCNR stimulated the systematic study of the effects of restructuring nursing practice environments on patient outcomes and on nurses practicing within them. The NCNR has funded three studies (two Cooperative Agreements and a research grant) to evaluate the impact of innovative nursing practice models in hospitals on the quality of care that is provided, on nurse retention, and on the costs to the institutions of the changes that are put in place. These models are designed to foster professional practice in clinical settings, to increase the ability of nurses to practice to the full expression of their clinical competence by designing patient care delivery methods that recognize the independent and interdependent functions of nursing and medical practice, and to expand the extent to which nurses are participating in clinical and managerial decisions. These five year studies are now into the second year; it will be some time before findings are available.

NCNR STAFFING

Question. It is our understanding that in FY90, NCNR expected to fill 29 full time equivalent (FTE's) positions out of 30 allowed. Have all staff vacancies been filled to date?

Answer. Early estimates of FY 1990 FTE usage, from projections based on on-board position strength at that time, predicted that NCNR would use 29 full time equivalent (FTE) man-years out of its ceiling of 30 FTEs. The Center has been actively recruiting to fill needed positions, in order to establish an Office of Planning, Analysis and Evaluation, and to continue staffing the new Collaborative Intramural Research Program. We expect to have a total of 34 positions filled by the end of FY 1990. The effort to fill 34 positions by year's end is also in keeping with the NCNR's plan to utilize 37 FTEs of staffing in FY 1991.

MINORITY STAFF

Question. Of the number of staff you currently have on board, how many are minorities and what positions do they hold?

Answer. The Center currently has four minority employees, equivalent to 14 percent of the on board staff, and is also assisted by a minority college student on a stay-in-school appointment. The staff members are a Personnel Management Specialist, an Administrative Clerk, and two Secretaries. The Center is also assisted by three retired scientists, one of whom is a minority. Efforts are continually underway to seek additional minority employees to work in the extramural programs of the Center. The pool of minority nurse researchers form which we can draw is very limited.

AIDS RESEARCH

Question. How much funding are you requesting to continue your projects in AIDS research? Are you planning to make any new awards in FY91?

Answer. The President's Budget request of $1,148,000 in 1991 will allow the NCNR to continue to support noncompeting AIDS research projects and research training. New AIDS projects will be awarded if the percentile scores achieved during review are high enough to merit funding.

Question. How is your research in this area progressing?

Answer. The physical problems of AIDS victims can be devastating -- shortness of breath, diarrhea, disorientation, frequent infections, fatigue and pain. NCNR has a commitment to support intramural and extramural research investigating strategies to reduce discomfort from physical symptoms associated with HIV infection.

Because the link between knowledge and behavior change is often weak, NCNR is also committed to conducting and supporting implementation strategies for community-based outreach and intervention programs to help people recognize the behaviors that place them at high risk for HIV infection, and then take the difficult step of changing them. Both the House and Senate committees and the Institute of Medicine's study of NIH AIDS research programs have stated the need for the scientific community to increase the quantity of HIV behavioral research. As of 1989, the majority of NCNR HIV/AIDS grants are studying behavioral research issues, such as prevention of HIV transmission, self care in the home, parental acceptance and care of gay men with AIDS. Examples of NCNR's behavioral research portfolio in AIDS prevention and patient care follow.

Studies are determining the extent of condom and spermicide use in two high-risk populations, sexually promiscuous adolescents and college students. NCNR is interested in funding further research to investigate other high-risk populations, such as persons using psychoactive drugs and partners of infected individuals.

Other investigators are identifying determinants of high-risk sexual practices among school and college-age persons. NCNR is interested in funding additional research in this area, particularly the study of sexual partners of HIV-infected, high-risk persons, minorities, prostitutes and individuals with learning disabilities.

MINORITIES IN NURSING RESEARCH

Question. How many minorities are involved in nursing research? What progress has been made, if any, in getting minority involvement in nursing research through minority institutions? Have the recommendations of the ad hoc advisory committee on minority training been acted upon? If so, what are some of the results? If not, when do you plan to pursue this effort?

It was indicated in last year's appropriation's hearings that an ad hoc advisory committee on minority training had advised NCNR take steps to supplement institutional training awards in order to gain more positions for pre- and post-doctoral fellows from minority applications.

Answer. In November 1989, the NCNR hosted a conference on Research and Research Training Opportunities at the NIH for Directors of Research from schools of nursing with graduate programs, and invited participants from those schools of nursing at minority institutions. All participants were informed about research and training grant support available through the NCNR and NIH, and procedures for successfully applying.

The Ad Hoc Advisory Committee on Minority Training recommended that the NCNR make special administrative supplements to existing institutional training grants specifically for minority nurse trainees, in instances where the training institution could demonstrate availability of suitable minority candidates. The 11 active institutional training grantee institutions were contacted, and two institutions succeeded in bringing three qualified minority candidates into their programs through supplemental awards. This strategy will be pursued further in FY 1990 and 1991.

The Committee also recommended that application procedures for new institutional training awards include special provisions for recruitment of minority nurse trainees. NIH guidelines require a minority recruitment plan as an essential component of the institutional training grant application. NCNR is working to clarify what the critical elements of such a plan are.

Overall, minority trainees increased from three in 1988 to nine in 1989. One of these is located at a minority institution. There are at least nine principal investigators on R01 research awards who are minority nurses and several others who are co-investigators.

The Center has also invited the nursing research community to apply for administrative supplements to existing research projects in order to involve minority investigators in the ongoing conduct of research. In 1989, one such supplement was awarded, several are under review, and it is expected that this tool will be employed more extensively in the future.

ALZHEIMER'S DISEASE AND THE BURDEN OF CARE

Question. What has been the response to your cosponsored program announcement with the National Institute on Aging concerning Alzheimer's disease and caregiving? Did a large number of applications come in for research concerning this issue?

Answer. There has been an increase in inquiries to NCNR about research opportunities related to Alzheimer's disease and caregiving, as a result of the program announcement, and potential applicants have been pleased to learn that this is an area of interest to NCNR. Program staff have visited one of the NIA supported Alzheimer's Disease Research Centers and have encouraged nurse scientists to link with scientists from all disciplines at these centers in an effort to develop interdisciplinary research on caregiving. It is too early to Identity specific numbers of applications that are in response to the program announcement. However, the support of research and research training in this field by the NCNR rose from $1.4 million in 1988 to $1.9 million in 1989.

Question. How much funding are you requesting for research to study the burdens of caregivers in FY91? What was the response in FY90?

Answer. Within the requested budget for FY 1991, the NCNR expects to support about $3,400,000. Special efforts are being devoted to encouraging research and training in this field on the part of the nursing research community, because of the vital importance of this work to elderly patients and to the persons providing their care.

In 1990, we estimate that research and training in this field may total about $2,400,000. A number of excellent research proposals are being received and funded.

NATIONAL NURSING RESEARCH AGENDA

Question. We understand the first major research priorities have been developed from the NCNR's long term planning endeavor, the National Nursing Research Agenda. Could you describe the scientific priorities? What program activities have been initiated for these scientific priorities?

Answer. The first two major nursing research priorities within the National Nursing Research Agenda are Low Birthweight -- Mothers and Infants, and HIV Infection -- Prevention and Care. A Priority Expert Panel for each of these areas has reviewed and refined the vital health questions relevant to nursing science. Reports on the promising areas for nursing research will inform the nursing and biomedical communities of each panel's findings and will be taken into consideration by NCNR in allocating resources. The report on HIV Infection -- Prevention and Care is close to completion and will be forwarded to Congress in the spring. The report on Low Birthweight -- Mothers and Infants will also be completed in FY 1990.

Drawing from panel deliberations on low birthweight, NCNR issued a program announcement on Neonatal Care of Low Birthweight Infants in December 1989. A program announcement entitled Research Related to Nursing Care of Persons with HIV was released in January 1989, and a program announcement is currently under development entitled Research on Symptom Management and Care of HIV-Positive Patients. While NCNR recognizes the importance to nursing practice of the research areas identified through planning, the process will not be allowed to dominate the allocation of nursing science dollars. Maximum support for competing applications in the two priority areas described above for FY 1990 has been set at approximately one third of available competing funds, in order not to overdirect the research, and allow investigator-initiated proposals to make up the bulk of the funded projects.

The future holds promise for even greater involvement of the nursing research community in this important process. The next three topics under development are Long Term Care of Older Persons, Information Systems for Improving Nursing Care, and Symptom Assessment and Management. The schedule for completion of this work is not firm but the panels are expected to finish in FY 1991. Since the issuance of each panel's report depends on the pace of a panel's work, the reports will become available sequentially as the work is completed. In the future the two final priority areas of Health Promotion with Youth and Adolescents, and Technology Dependency Across the Lifespan will be developed.

RESEARCH CENTERS

Question. What is the progress of the new Centers program initiated by Congress in 1989? How many applications did you receive and how many did you fund? What type of growth is needed for this new program?

Answer. The NCNR announced in November 1988 the new Research Centers program mandated by the Congress, and invited two kinds of applications -- specialized centers and exploratory centers. The specialized center grant supports the creation of an interdisciplinary collaborative program among established investigators in a specific area of basic or clinical research. The specialized center grant provides for the integration of a group of related projects, and encourages the development of new research projects, and provides an enhanced environment for research training and career development. The exploratory center grant enables institutions with a limited amount of ongoing research to strengthen their research capabilities, increase productivity, and generate new research through formal interdisciplinary collaborative efforts. The exploratory center grant supports pilot and feasibility studies, shared resources, and administrative activities in support of research.

A total of 11 applications for specialized centers and 32 applications for exploratory centers were received. The NCNR was able to award two of each type of center in 1989.

The first Specialized Center is at the University of Washington, with six research projects to be conducted in women's health across the lifespan. Research topics will include health seeking behaviors among midlife women, intestinal response to ovarian hormones and dietary fiber, and recovery from alcohol and benzodiazepine use. The second specialized center is at the University of Pennsylvania, conducting research in advancing care in serious illness. Research will be carried out in the areas of recovery from colorectal surgery, depression in stroke patients, and the health effects of bereavement.

One Exploratory Center is at the University of Pittsburgh, and is emphasizing research on critical care nursing. The second exploratory center is at the University of Minnesota, with an emphasis on Long Term Care of the Elderly.

The future growth of this program will depend on the availability of funds, but there is clearly a need for both of these types of research support. There are many nursing schools whose research programs are established, though not as intensive as those of other schools, which will profit from exploratory centers. There are several schools with advanced research programs which could raise their productivity even further with the focused support and shared resources inherent in a specialized center. In my professional judgement, and based on the advice of the National Advisory Council for Nursing Research, the program should require 2 or 3 more of each type of center in steps, to reach at least 8 specialized centers and 11 exploratory centers.

RESEARCH TRAINING INITIATIVE

Question. The nursing research community has expressed the need for a strong initiative in research training for nurses. What have you done in this area and what remains to be done? The nursing research community has also been concerned with post-doctoral education and support. What postdoctoral training is NCNR supporting?

Answer. When the first permanent Director of the NCNR was appointed, an examination of possible new directions for the programs in nursing research revealed a great need for a strong training program. The National Academy of Sciences recommended a level of 320 trainees annually, and the NCNR defined a training initiative to reach that goal over several years. The NCNR completed the second step of that initiative in 1989, with the support of 228 trainees through fellowships, institutional training awards, and research career awards. This represents considerable progress from the starting point of the initiative in 1987 of 171 trainees, and we expect to advance to a total of 257 trainees in 1990. The request for 1991 allows the same number of trainees to be supported as in 1990.

The need for increased postdoctoral training is linked to the maturing of a research community with an advancing science. The NCNR has worked to increase both the number of postdoctoral trainees, as well as the proportion within an increasing total of trainees. They have grown from 17 in 1987 to 41 in 1989, and the

Center expects to increase the number to 52 in 1990 and 1991. The proportion was 10 percent in 1987, and will rise to 20 percent in 1990 and 1991. Part of this increase represents new emphasis on the mechanisms of academic investigator awards and clinical investigator awards.

COLLABORATIVE INTRAMURAL RESEARCH PROGRAM

Question. What type of scientific opportunities are being pursued in the new Collaborative Intramural Program? What types of studies will you be conducting? Do you plan to expand into other areas of nursing research other than just AIDS?

Answer. The first emphasis within the NCNR's new Collaborative Intramural Research Program will be an organized program of basic and clinical research to increase the understanding of, and develop nursing interventions for, the health problems that are particularly common among individuals with HIV infection, their families, or their caregivers. The ultimate goal of this research program is to minimize dysfunction and suffering due to physical or psychosocial consequences of HIV infection, and to explain the underlying mechanisms. Examples of these problems are: unintentional weight loss, decreased appetite, or other nutritional disorders; fatigue; dementia, confusion, or other cognitive disorders; diarrhea; and mouth sores and oral discomfort. Other common behavioral problems such as anxiety, depression, loss and grieving, and quality of life are also within the purview of the NCNR intramural research program.

Future growth of the intramural program will proceed in a measured manner into other fields of clinical research at the National Institutes of Health which provide excellent opportunities for nursing research to utilize existing resources and patient populations. It appears that the care of cancer patients may be a promising area for research expansion, as well as research into care of the aging.

HEALTH AND BEHAVIOR

Question. What studies are being supported by NCNR in health and behavior? What percentage of the Center's budget is committed to health and behavior research?

Answer. Within its mission to support basic and clinical research that impacts on patient care, NCNR supports research on the behavior of patients and care providers related to health and illness. Three major areas under study are recovery from cardiovascular illness, coping with cancer and its treatment, and management of chronic diseases. Recovery patterns of older women after myocardial infarction are being examined to determine how to assist these women in returning to maximal functioning. Another study is identifying coping behaviors utilized by patients who have undergone cardiac surgery, to evaluate the beneficial effects of behavioral interventions. In other research, behavioral strategies for coping with cancer and cancer treatments are being tested, seeking to help the patient minimize the unpleasant and debilitating side effects of cancer treatment.

Behavioral management of chronic diseases are also being studied, with current research in diabetes, asthma, depression, osteoporosis, hip fracture, urinary incontinence, and obesity.

Behavioral Research in FY 1989 totaled $12,558,000 and represented about 47 percent of NCNR extramural funds. NCNR supports approximately 5 percent of the behavioral research supported and conducted by the NIH.

MINORITY RESEARCH AND TRAINING

Question. What program initiatives does NCNR have for supporting research with minority related research as well as supporting research training for minority colleagues?

Answer. The Center supports a variety of research on health problems disproportionately affecting minority populations. These are in the fields of prevention of infant mortality and low birthweight, controlling hypertension among older minority populations, prevention of HIV transmission and care of AIDS patients, and research on caregiving and the long term care of older persons.

NCNR is committed to increasing the number of minority nurses involved in research. The Center is participating with other NIH Institutes in the regional minority meetings held to encourage native Americans and Hispanics' involvement in research. NCNR is also planning a special task force meeting for the Summer of 1990 to discuss nursing research issues and research training in relation to the special needs of minorities, as well as American Indians, native Alaskans and Hawaiians. The goal will be to define a framework for new directions of research on the health care problems of these populations, and strategies to seek solutions.

NCNR is also committed to increasing the number of minority nurses involved in research. The Center is participating in an initiative with other NIH institutes to provide special research opportunities for minority faculty and students through supplements to existing research awards. Supplements may be for research assistants or for minority faculty to work collaboratively with the principal investigator. In the area of training, the NCNR has funded slots for minority trainees on existing institutional training grants, and requires all training grants to develop a minority recruitment plan.

NCNR has required the new Specialized Centers of Nursing Research to include minority outreach as a part of their programs. The Specialized Center applicants identified several innovative approaches to involving minorities in nursing research, such as linking with minority schools, supplementing projects with minority research assistants, and identifying minority clinical specialists to assist in including minorities in the study populations.

RESEARCH PROJECT GRANT AWARD RATES

Question. Dr. Hinshaw, how many competing research awards do you plan to fund in FY 1991? How does this compare to the number of competing awards made in the past several years? What will be the award rate for NCNR in FY 1991? How does this compare to the predicted NIH award rate? How much additional money would it take to achieve at a minimum a 25% award rate in FY 1991?

Answer. In 1991 the NCNR plans to fund 33 competing research project grants due to the rising number of noncompeting grants in a growing program. This compares to 45 competing research project grant awards in 1990, 50 competing awards in 1989, and 52 awards in 1988.

The award rate which the Center will be able to achieve in 1991 is estimated to be 12 percent. This compares to award rates for NCNR of 19 percent in 1990, and 25 percent in 1989. These award rates contrast with NIH as a whole, which had a 29 percent rate in 1989, and is estimated to achieve a 24 percent rate in 1990, and a 25 percent award rate in 1991.

In order to achieve the standard of a 25 percent award rate for the Center, 71 competing awards would need to be funded in 1991. The full cost of these awards would be approximately $17,083,000, or $10,339,000 more than the competing funds which have been requested.

REDUCTION OF RESEARCH PROJECT GRANTS

Question. What is the anticipated downward negotiation rate of both competing and noncompeting awards in FY 1991 as compared to FY 1990 and 1989? If this is greater in 1991, why aren't you funding more, rather then less, competing RPGs?

Answer. The downward negotiation rates for research project grants in 1991 for the NCNR are 16.5 percent on competing and 17.8 percent on noncompeting awards. In 1990 the rate is 12 percent for both noncompeting and competing, and in 1989, the rate was 10 percent.

Another complicating factor is that as a relatively new program within the NIH, the NCNR has experienced a rapid growth in average grant size typical of new programs. The average size is expected to reach a plateau, as grants of most other Institutes have, at a natural sized research project for the particular sector of science, with a much slower growth following. The Center's projects are still in the initial growth phase, resulting in greater demand for both noncompeting and competing funds.

In 1991, the Center's goal will be to place as many competing awards in the field as possible. This makes the projected reductions necessary, while yielding 33 competing awards.

RESOURCES FOR RESEARCH MANAGEMENT AND SUPPORT

Question. Dr. Hinshaw, there is very little increase requested for the RMS activity in FY 1991. Now that the Center is growing and doing so well, don't you have additional needs for more FTEs, supplies and equipment? Can you continue to effectively service the community with the dollars requested in RMS?

Answer. The Research Management and Support budget for 1991 provides for the expected increases in mandatory cost items such as salaries and central service taps, as well as some inflation in the cost of the same level of the remaining kinds of materials and services utilized in 1990. With a young and growing program, great care must be taken to select the most important uses for limited funds, and the NCNR has chosen increased staffing as the most urgent use of funds. The request will allow an increase of five FTEs for employment in RMS, in order to establish planning and computer services, and to augment the extramural program staff, which is faced with an increasing array of granting activities and a rising tide of applications. The Center will seek to pay for the increased salary costs by reducing purchases of equipment and slowing the pace of the multi-year national research planning process.

COLLABORATIVE INITIATIVES

Question. Would you please supply a list of those projects (awards) funded which incorporate the National Center for Nursing Research and the National Institute on Aging?

Answer. There are currently three initiatives involving the NCNR and the National Institute on Aging (NIA) with shared funding and monitoring of projects: incontinence studies; Alzheimer's disease and the burden of care; and frail elderly and the prevention of falls. The incontinence studies have been a collaborative effort since the nursing research programs were transferred from the Division of Nursing in HRSA in 1986 to establish the NCNR, and is currently in its final stage with funding tapering off. The initiative on Alzheimer's disease and the burden of care was established in 1989, with special announcements to the nursing science community, as was the initiative on care of the frail elderly and prevention of falls.

While collaborating with NIA, the NCNR retains responsibility for selecting the science and funding projects which are oriented to nursing practice and reflect the mission of NCNR. The staff works with NIA staff to coordinate the overall administration of the projects. The dollar figures listed below are those spent by on projects selected by the NCNR, even if a specific project is also partially co-funded by the NIA.

Urinary Incontinence

Dr. John Schnelle Middle Tennessee State University	$116,495	Behavioral Management of Urinary Incontinence

Alzheimer's Disease -- Research

Dr. Virginia Neelon University of North Carolina	333,476	Confusion in Hospitalized Elders
Dr. Mary Naylor University of Pennsylvania School of Nursing	294,705	Comprehensive Discharge Planning for the Elderly
Dr. Linda Phillips University of Arizona College of Nursing	184,949	Relationships Affecting the Quality of Family Caregiving
Dr. Mary Quayhagen University of San Diego	110,409	Cognitive Stimulation Training in Alzheimer's Families
Dr. Joan Magilvy Older University of Colorado Health Sciences Center	143,286	Rural Home Care for Adults: Pattern and Process

Alzheimer's Disease -- Training

Fay Reilly University of Kentucky	12,500	Space and Time Use by the Elderly
Margaret England Case Western Reserve University	12,500	Evaluation of a Model of Parent Care, Stress and Strain
Janean Holden University of Michigan	12,500	Disorientation and Environmental Cue Use in Rats
Rebecca Johnson University of Iowa	12,500	Reminiscence Therapy: A Nursing Intervention for Elders
Michele Clark University of Texas	20,000	Impact of Structured Nursing Intervention on Burden
Martha Worcester University of Washington	20,000	Kin Care of Frail Elders: Social Networks and Respite
Ann Yurick University of Pittsburgh	30,651	Multivariate Research: Application to a Nursing Model
Dr. Donald Price Johns Hopkins University	82,000	Education Supplement to NIA Alzheimer's Disease Research Center

Dr. Leonard Berg	79,500	Education Supplement to NIA Alzheimer's Disease Research Center

Care of the Frail Elderly

Dr. Meridean Maas University of Iowa	500,000	Nursing Intervention for Falls: A Field Experiment

MINORITY NURSE TRAINING

Question. Give us an update on the effort to increase minority nurses in research training.

Answer. The NCNR formed an Ad Hoc Advisory Committee on Minority Training, to advise the Center on appropriate strategies to increase minority participation in the research training programs. The committee recommended that the NCNR make special administrative supplements to existing institutional training grants specifically for minority nurse trainees, in instances where the training institution could demonstrate availability of suitable minority candidates. NCNR's eleven existing grantee institutions were contacted, and two of them succeeded in bringing qualified candidates into their programs through supplemental awards in 1989. Further activity is expected through this mechanism in 1990 and 1991.

The Committee also recommended that application procedures for new institutional training awards include special provisions for recruitment of minority nurse trainees. The guidelines for minority recruitment are being revised for all NIH institutional training grants. Information is being disseminated that NCNR requires as an essential element of all applications the inclusion of a recruitment plan for minority trainees.

The Center also invited the nursing research community in 1989 to apply for administrative supplements to existing research projects in order to involve minority investigators in the conduct of the research. In 1989, one training supplement was awarded, several others are under review, and it is expected that this tool will be employed more extensively in the future.

In November 1989, the NCNR hosted a conference on Research and Research Training Opportunities for Directors of Research from schools of nursing with graduate programs. Special attention was given to schools of nursing at minority institutions, which were invited to send additional participants. The participants were informed about research and training grant support available through the NCNR and NIH, and procedures for successfully applying.

RURAL HEALTH RESEARCH

Question. What initiatives has the National Center for Nursing Research undertaken concerning nursing and the improvement of patient care in rural America.

Answer. The National Center for Nursing Research has been collaborating with the Division of Nursing of the Health Resources and Services Administration and the newly established Agency for Health Care Policy and Research in the development of an initiative that will focus on improving the health of minority persons living in rural areas. This work has recently culminated in a joint decision to support research and demonstration projects that will study the implementation of replicable community-based nursing practice models for providing health care to minority persons living in rural areas. This effort is titled "Research Demonstration on Community-Based Rural Health Care Models for Minority Populations." A request for applications that will communicate our agencies' interest in receiving grant applications in this area will be published in the NIH Guide to Grants and Contracts on March 9, 1990. It is anticipated that two or three applications will be funded in FY 1990.

PROFESSIONAL JUDGMENT BUDGET

Question. In your professional judgment, what additional resources and money would you like to see allocated to the Center in Fiscal Year 1991?

Answer. In my professional judgment, now that the Center has in place solid foundations for substantial extramural and intramural programs, and the community has responded vigorously with numerous proposals for valuable research, the time is right for a major move forward. I will prioritize my opinions on the most vital needs of the Center by funding mechanisms:

1. $7,890,000 would allow restoration of noncompeting and competing research project grants to a 7 percent reduction level, and would increase the number of competing awards to 57, equivalent to a 20 percent award rate.

2. $2,473,000 would permit the second step in development of the research centers program, by adding 3 specialized centers and 4 exploratory centers.

3. $631,000 would allow attainment of the third step of the training initiative, adding 17 trainees to the NRSA program and 6 research career awards, for a total of 280 trainees in 1991. This would include the initiation of the planned Nurse Scientist Award.

4. $433,000 added to the Collaborative Intramural Research Program would permit initiation of the next clinical protocol for nursing care research with HIV-positive patients in the NIH Clinical Center.

5. $3,255,000 in research project grants would bring the number of competing awards to 71, thereby attaining a 25 percent award rate. All of the awards would be reduced 7 percent.

6. $576,000 in Research Management and Support would allow staffing changes without loss of other services or delay of the national planning process to develop a National Nursing Research Agenda.

These needs could all be satisfied with a 1991 budget of $50,385,000 for the NCNR.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

HEALTH PROFESSIONS TRAINING PROGRAMS

Question. Dr. Hinshaw, the President's budget for fiscal year 1991 recommends terminating federal support for health professions training programs in the field of Nursing. In your professional judgment, is there no longer a need for federal-support for these programs? What is the status of the "shortage" in nursing the Committee has heard about for the past several years?

Answer. The nursing shortage remains a problem for the profession and for the health care industry, although some of the latest information available suggests that there might be a slight easing of the shortage. Data from the American Hospital Association indicate that the vacancy rate for employment of registered nurses in hospitals has declined slightly from 1987 to 1988, but is still above 10 percent. There is also good news concerning the number of first-time enrollments in basic nursing education programs, with increases over the past two years. However, even after this rise, the enrollments are far short of the high point experienced in the 1983-1984 academic year.

In my professional judgment, to withdraw support for the health professional training programs in the field of nursing would be a mistake. There are clearly problems remaining in the health care industry, and we need to consolidate the gains of the last two years. This is our opportunity to reinforce the limited increase in enrollment through support of the health professional training programs in the field of nursing.

NURSING SHORTAGE

Question. Has the Center supported research examining the adequacy of the pool of nurses in our country?

Answer. The responsibility for the needed manpower studies to examine the adequacy of the pool of nurses in the country, and for preparing the mandated Congressional biennial report on the findings of these studies is that of the Division of Nursing of the Bureau of Health Professions, Health Resources and Services Administration. The latest findings are included in the Seventh Report to the President and the Congress on the Status of Health Personnel in the United States. Dr. O. Marie Henry, Director of the Division of Nursing can provide further amplification of this subject.

RESEARCH PROJECT GRANT AWARD RATES

Question. Dr. Hinshaw, the Committee continues to be concerned about the level of approved grants receiving funding at the NIH. What percentage of approved grants do you anticipate funding under the President's FY '91 budget?

Answer. The research project grant award rate for FY 1991 will be 12 percent for the National Center for Nursing Research.

Question. How does this compare with FY '89 and FY '90?

Answer. In FY 1989 the NCNR awarded 25 percent of the approved competing applications, and expects to award 19 percent in FY 1990.

Question. Will this decline impact the Center's ability to carry-out the NCNR's Priority Research Agenda?

Answer. As each Priority Expert Panel completes the work of defining and prioritizing the topics of most urgency and scientific promise within each area, the results will be widely reported to the scientific community, to influence the choice of research plans by investigators. The Center will also issue direct invitations to the field, through program announcements and requests for applications.

However, the intent of the Center is to balance these priority areas with the need to allow the bulk of research proposals to remain investigator-initiated. The priority areas will not be protected as support is reduced. The decline in award rate will reduce the emphasis on priority areas, such as prevention and care of low birthweight infants, just as it will reduce the rest of the competing portfolio.

NATIONAL CENTER FOR HUMAN GENOME RESEARCH

STATEMENT OF DR. JAMES DEWEY WATSON, DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Watson, Director of the National Center for Human Genome Research, you are charged with managing the most aggressive and perhaps most important scientific project ever launched—that is my own view, as you can probably tell from what I have said earlier today.

We look forward to hearing your statement. You are asking next year for $108.03 million, for a modest 81.45-percent increase—modest, in light of the job ahead of you I might add. Please proceed.

Dr. WATSON. Mr. Chairman, with your permission, I will read my short statement. The mission of the newly established National Center for Human Genome Research is to lead the NIH component of the worldwide research effort now popularly called the Human Genome Project.

The goal of this endeavor is to determine the order or the sequence of the subunits of human DNA, the substance that makes up our genes. Doing so will allow us to identify and locate all the genes that comprise the human genome.

Deciphering genetic information encoded within our genes will provide important insights into the molecular roots of health and disease.

With rigorous planning and coordination with the Department of Energy we have now developed a broad and orderly approach to tackling the many and diverse challenges surrounding the genome project.

Briefly, the goals that we have established through fiscal year 1995 are to develop the genetic and physical maps of the human genome, including overlapping clone sets for several chromosomes; improve the cost and efficiency of DNA sequencing methods; map and begin to sequence the genomes of several model organisms; develop computer technology for handling genome data; examine the ethical, legal and social issues raised by the availability of genetic information and develop policy options; train researchers; support innovative technology development; and transfer genome project technology to United States industries for development.

To achieve our goals, genome scientists are finding ways to rapidly isolate, reproduce and analyze long segments of human DNA. Scientists have now used modified yeast chromosomes to isolate and clone human DNA segments spanning a length of 2 million nucleotides, the chemical subunits of DNA.

Finding new genetic markers on all the human chromosomes will streamline research efforts to map the human genome. Several grantees have played a key role in finding new types that will fill in gaps and allow mapping to be done more easily, perhaps even by automation.

Recently, genome scientists developed a system which used markers called "sequence tag sites" that will help unify the various mapping techniques used today.

We have also made headway in developing methods to speed up sequencing the nucleotides in human DNA by improving current sequencing machines and automating additional steps in the process.

Foremost among our initiatives is the establishment of multidisciplinary genome research centers. Housing experts in complementary scientific fields, these centers will offer resources and collaboration and technology transfer opportunities to genome researchers in government, academia, and industry. In fiscal year 1990 we expect to fund 3 of these centers. In fiscal year 1991 we hope to raise that number to 9 and plan to fund up to 20 in the next few years.

The ethics working group chaired by Dr. Nancy Wexler of Columbia University has made significant progress in focusing on the social, ethical, and legal issues raised by the availability of genetic information. We have already received a number of ethics grant applications and plan to strengthen that program further. In fiscal year 1991 we hope to begin town meetings around the country to educate and seek public views about this program.

PREPARED STATEMENT

Mr. Chairman, if the short history of the National Center for Human Genome Research is an example, I have every confidence that our future will be productive and promising.

Our budget request for fiscal year 1991 is $108,029,000. I will be happy to answer your questions.

[The statement follows:]

STATEMENT OF DR. JAMES DEWEY WATSON

Mr. Chairman, and members of the subcommittee, it is my pleasure to appear before you today for the first time as director of the newly established National Center for Human Genome Research. Our mission is to lead the NIH component of the worldwide research effort now popularly called "the human genome project." Being before this subcommittee today is particularly significant because the budget for genome research has reached a level from which we can formally launch the 15-year human genome project. The goal of this endeavour is to determine the order, or sequence, of the subunits of human DNA, the substance that makes up our genes. Doing so will allow us to identify and locate all the genes that comprise the human genome. The task is both tremendously important and formidable.

Recognizing the growing role the National Institutes of Health has played in the human genome project, Secretary Sullivan formally established the NIH National Center for Human Genome Research in October of 1989. Before that time, our business was conducted as part of the NIH director's office, where we were called the Office for Human Genome Research.

We have watched the human genome project be transformed from an ambitious idea--some said overly ambitious--into a reality. In the past year, we have developed a broad and orderly approach to tackling the many and diverse challenges surrounding the genome project. Deciphering the genetic information encoded within our DNA will provide an important handbook to explain how we function as healthy human beings. It will also provide us with a new understanding of the genetic components of such widespread illnesses as heart disease, high blood pressure, diabetes, and many, if not all, cancers. As we enter the last decade of this century, we are ready to proceed with a project that will have a profound impact on the biological science of the next century.

Locating individual genes on a chromosome and then analyzing the DNA components that make up these genes is now possible for increasingly complex genomes. The National Institutes of Health has supported much of the basic research that has brought us to this threshold, particularly research emanating from the invention of recombinant DNA technology in the early 1970s. Because of the generous funding provided by the Congress to the National Institutes of Health, the United States is clearly a leader in the science of gene mapping and sequencing.

How will we use this scientific leadership to achieve our goal? This past August, advisors to the National Institutes of Health and the Department of Energy met to plan our collective mission over the next 5 years of this project. The scientific experiences of our respective agencies dovetail remarkably and bring complementary strengths to the human genome project. After vigorous planning and coordination, our path is now well charted and _A Five-Year Plan for the Human Genome Project_ was issued. Briefly, the goals we have established for fiscal years 1991 through 1995 are: 1) to map in detail the human genome, both genetically and physically; 2) to improve the efficiency of DNA sequencing methods to reduce the cost to an acceptable level; 3) to map and in some cases begin to sequence the genomes of selected model organisms; 4) to develop computer and other information technology for storing and analyzing map sequence data; 5) to identify and examine ahead of time the ethical, legal and social issues raised by the availability of genetic information and develop policy options to address them; 6) to train researchers in the combined areas of scientific expertise needed to map and sequence the human genome and to interpret the resulting information; 7) to support innovative technology development as well as improvements in current technology to meet the needs of the human genome project; and 8) to transfer technology invented as part of the human genome project to U.S. industries for development into useful commodities that will improve the quality of life for Americans and compete favorably in the international marketplace.

As part of the August planning meeting, we evaluated the state of the science of gene mapping and sequencing. We were excited by the rapid progress that has taken place over the past two years. In that time, many promising gains have been made in the technology of mapping and sequencing. Mapping refers to identifying the location of genetic or physical landmarks on chromosomes. The so-called "physical" map of the human genome uses nucleotides, the chemical subunits of DNA, as its unit of measure. Over the years, many different, and often exclusive, methods have been developed for determining nucleotide distances between recognizable landmarks, such as genes. On the one hand, these diverse methods have allowed scientists to make great strides in fashioning physical maps. On the other, they have made comparing information in maps produced by different methods very difficult, if not impossible. This past summer, four genome scientists proposed a system that promises to be the "Rosetta Stone" for physical maps. This system uses markers called "sequence-tagged sites," or STSs, that can be incorporated into any mapping technique used today. Scientists working in different laboratories, using different techniques, can now add their results to a common physical map that will be available to and usable by all genome researchers. The properties of STSs will allow scientists to use them to regenerate any desired piece of DNA in their own laboratories--an advantage that will reduce dependence on centrally stored DNA pieces.

During fiscal year 1990 we are developing and refining the STS idea. Our advisory council has established a joint working group with the DOE to discuss the establishment of a pilot program for converting existing markers to the STS system and for a central computer database for STS information. We hope to begin this program in 1991.

Another hurdle physical mappers have faced is finding ways to isolate and reproduce long segments of human DNA for analysis. Recently, Dr. David Schlessinger, at Washington University in St. Louis, used modified yeast chromosomes to isolate and clone several overlapping segments of human DNA from the X chromosome. In all, these segments spanned a stretch 2 million nucleotides long. This achievement, which has produced the longest continuous region of human DNA ever cloned, greatly advances our efforts to produce a complete physical map because it demonstrates that our 5 year goals for physical mapping are indeed achievable.

Usually, genes located near each other are passed on together in a "linked" way to the next generation. Maps called genetic "linkage" maps, designed to track disease genes from one generation to the next, rely on knowing the location of easily identifiable genetic markers that are routinely passed along with specific disease genes. Finding enough of such markers on all the human chromosomes will streamline our research efforts and help other efforts to isolate and analyze disease genes. ~~NCHGR~~ grantees have played a key role in adding landmarks to the current genetic linkage map. Dr. Helen Donis-Keller of Washington University in St. Louis, has been working to narrow the gaps between markers. Dr. Raymond White, at the University of Utah, is focusing on regions of the map that contain few markers. As part of his project, Dr. White is also developing markers that can be translated usefully to the physical chromosome map.

Several grantees are looking for new types of linkage markers that will allow gaps to be filled and mapping to be done more easily, perhaps even by automation. One example is the "CA repeat," a new type of marker developed by a number of scientists, including Dr. James Weber at the Marshfield Medical Research Foundation in Wisconsin. The number of CA repeats at a given site in DNA can be used as a genetic marker because it differs from person to person and can be analyzed using the powerful new polymerase chain reaction to trace its inheritance from one generation to the next.

Sequencing all of the 3 billion nucleotides in human DNA is the human genome project's ultimate goal. Recently, the NCHGR supported a major conference at Wolf Trap, Virginia, to bring biologists doing DNA sequencing together with technology experts to discuss the state of the science of sequencing large pieces of DNA. We are encouraged by the consensus of the many top-notch scientists at that first Genome Sequencing Conference: sequencing technology is improving; the automated DNA sequencers are reliable and useful for sequencing large DNA stretches.

However, these are first-generation machines. The time, labor, and expense even these machines now require dictate that significant improvements in DNA sequencing methods are still required before we can completely sequence human DNA. Dr. Leroy Hood, at the California Institute of Technology, for example, has used machines to sequence a stretch of human DNA 70,000 nucleotides long, in about 7 months. With continued improvements in these machines, in the associated computer programs and in automation of other steps in the sequencing process, Dr. Hood expects to increase the capability of automated sequencing to about 50,000 nucleotides per week. We are also supporting research and development of entirely new approaches to sequencing, realizing that the best technology for this job may not yet have been invented.

To assure that mapping and sequencing technology development moves as rapidly as possible, we plan to continue sponsoring a variety of conferences and workshops. The next sequencing conference, for example, is set for the end of this year in South Carolina.

Mapping and sequencing the human genome demands the coordinated, labor-intensive efforts of specialists in a variety of scientific fields. Foremost among our initiatives is the establishment of multidisciplinary genome research centers. Housing experts in genetics, molecular biology, as well as in computer science and even physics, these centers will serve as the centerpiece of the genome project and will offer resources and collaboration and technology transfer opportunities to all genome researchers. In fiscal year 1990, we expect to fund three of these centers. In 1991, we hope to fund 9 and plan to fund up to 20 in the next few years.

While the knowledge gained from genome information will undoubtedly lead to many health benefits, we recognize the many concerns that possession of such information may pose. The joint NIH-DOE ethics working group, chaired by Dr. Nancy Wexler at Columbia University, has made significant progress in focusing our program on the social, ethical, and legal issues raised by the availability of genetic information. About 3 percent of the NCHGR budget will go toward this research. We have already received a number of grant applications to study these very important issues, and hope to fund many more grants in fiscal year 1991. In 1991, we also plan to begin "town meetings" around the country to educate the public about this program and to seek their input on these matters.

Mr. Chairman, I have been enthusiastic about the human genome project from the time the idea was born. But I could not have predicted then that it would take such positive shape as quickly as it has in these past 2 years. If our short history is an example, I have every confidence that our future will be productive and promising.

The budget request for the National Center for Human Genome Research for fiscal year 1991 is $108,029,000. I will be happy to answer your questions.

BIOGRAPHY OF DR. JAMES DEWEY WATSON

Birthdate:	April 6, 1928 - Chicago, Illinois
Education:	1947 - B.S., Zoology, University of Chicago 1950 - Ph.D., Zoology, Indiana University

Professional Career:

1950-51	Research at the University of Copenhagen with H. M. Kalckar
1951-52	Research at Cambridge University in the Cavendish Laboratory
1953-55	Senior Research Fellow in Biology, California Institute of Technology
1955-56	Research at Cambridge University in the Cavendish Laboratory
1956-58	Assistant Professor of Biology, Harvard University
1958-61	Associate Professor of Biology, Harvard University
1961-76	Professor of Biology, Harvard University
1968-	Director of the Cold Spring Harbor Laboratory

1988-89	Associate Director for Human Genome Research, NIH
1989-	Director, National Center for Human Genome Research, NIH

Awards:

The John Collins Warren Prize of the Massachusetts General Hospital (with F.H.C. Crick), 1959
Eli Lilly Award in Biochemistry, 1960
Albert Lasker Prize (awarded by the American Public Health Association), 1960
Research Corporation Prize (with F.H.C. Crick), 1962
Nobel Prize in Medicine (with F.H.C. Crick and M.H.F. Wilkins), 1962
John J. Carty Gold Medal of the National Academy of Sciences, 1971
The Presidential Medal of Freedom, 1977

Honorary Degrees:

D.Sc., University of Chicago, 1961
D.Sc., Indiana University, 1963
L.L.D., Notre Dame University, 1965
D.Sc., Long Island University (C.W.Post), 1970
D.Sc., Adelphi University, 1972
D.Sc., Brandeis University, 1973
D.Sc., Albert Einstein College of Medicine, 1974
D.Sc., Hofstra University, 1976
D.Sc., Harvard University, 1978
D.Sc., Rockefeller University, 1980
D.Sc., Clarkson College, 1981
D.Sc., State Univ. of New York, Farmingdale 1983
M.D., Buenos Aires, Argentina, 1986

Professional Affiliations:

American Society of Biological Chemists
American Association for Cancer Research

Honorary Affiliations:

American Academy of Arts and Sciences (1958)
National Academy of Sciences (1962)
Danish Academy of Arts and Sciences (1963)
Honorary Fellow, Clare College, Cambridge University (1968)
American Philosophical Society (1977)
Atheneum (London) (1980)
Royal Society (London) (1981)

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Dr. Watson, thank you very much. I followed that with interest. I appreciate that. I will have some more questions in a second here.

[The following questions were not asked at the hearing, but were submitted to the Center for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

COORDINATION OF FEDERAL EFFORTS

Question. Dr. Watson, of course you know the Department of Energy also has a human genome effort underway. Could you describe, for the Committee, the mechanisms in place to ensure that the NIH and the Department of Energy efforts are well coordinated?

Answer. The NIH and the DOE have had an excellent working relationship with respect to the Human Genome Project in the past and we expect that this relationship will become even better as the program develops. The basic mechanisms for coordination of human genome activities between the two agencies are specified in a 1988 Memorandum of Understanding. As called for in this document, a joint advisory subcommittee was established to monitor and coordinate programs. The membership of this joint subcommittee comprises members of the NIH Program Advisory Committee on the Human Genome and the DOE Health and Environmental Research Advisory Committee.

Additional joint working groups have been established to address a number of programmatic issues. These include a joint informatics working group, a joint ethics working group, and a joint mapping working group. This approach has worked successfully to date in helping the agencies coordinate their development of program plans and policies and we expect that additional joint working groups will be established as needed.

In August 1989, a group of NIH and DOE advisors and staff met, together with selected other experts, to jointly develop a 5 year plan for the Human Genome Project. Because of the success with which we regard the joint planning exercise and the need for frequent updates of the plan in light of the rapid advances occurring in the area of genomic research, the two agencies will repeat this process at regular intervals. This will help to ensure continued close coordination.

Finally, there is extensive formal and informal contact between the two agencies at the staff level.

Question. Also, what mechanism do you have in place in insure that the projects funded by NIH will not duplicate each other and cover the same sections of the sequence.

Answer. All applications to the NCHGR for support of genome-related research are peer reviewed for technical merit by an initial review group. They are also individually considered for program relevance by a National Advisory Council. The Council makes recommendations to the NCHGR staff with respect to program balance, opportunities for new advances, and other factors. Information on currently supported projects is provided to reviewers, so that they can take this into account.

GOALS OF THE HUMAN GENOME PROJECT

Question. I understand that there is a 15-year target for having the basic map and sequence finished. Of course with approximately 100,000 genes and 3 billion sub-units which make up those genes, this is an enormous task. How optimistic are you that we will be able to meet the 15-year time table?

Answer. I am quite optimistic that we will be able to do so. The way in which interest in the project has increased within the scientific community over the past 2 to 3 years and the rate at which scientific advances have been made during this time has only increased my conviction that the goals that we have set for ourselves can be met.

Of course, it is also true that this is still an ambitious task. Further scientific progress and new technology will be needed to meet these goals. If we had to rely completely on the techniques and strategies available to us today, it is unlikely that we would finish the job in 15 years. That is why the strategy we have outlined in the 5-year plan emphasizes the development of new technology for both mapping and sequencing during the initial phases of the project.

I would also like to emphasize that we will not have to wait for 15 years to reap benefits from this program. Certainly, the technological advances that will be forthcoming in the next few years will have immediate applications in other areas of biomedical research, such as the identification and analysis of genes associated with diseases. However, what does not seem to be widely appreciated is that map construction and sequence accumulation are incremental processes. Each time a new marker is added to the map or a new region of a genome is sequenced, the maps and sequences become more useful tools. Thus, I believe that we will be able to point to successes of this program starting in the very near future and continuing for the next 15 years and beyond.

FUNDING PLAN

Question. When the original consensus conference completed its work and recommended the establishment of the Human Genome project, it was recommended that your budget would build and be maintained at a $200 million level over a 3 to 5 year period. Is this still what you consider to be a reasonable funding scenario for this project?

Answer. Yes. I believe that it is important for the budget for the Human Genome Project to reach the $200 million level rapidly. This level, in constant dollars, should allow us to achieve our outlined goals in about 15 years.

ROLE OF THE HUMAN GENOME RESEARCH CENTERS

Question. You have stated that you see the Human Genome Centers as being the center piece of the genome program. Specifically what role do you imagine these centers playing in the community beyond being centers of research?

Answer. Each genome center will have a specific research goal related to one of the major goals of the human genome program, as identified in our national plan. This will naturally lead to each center becoming the focus for collaboration with other scientists working on related research efforts. All of the centers will be expected to have an outreach component through which they will facilitate the distribution of resources and information from the center to the rest of the interested scientific and industrial community. In addition, the centers are expected to serve as a means of coordination for information and resources for the field.

TECHNOLOGICAL BREAKTHROUGHS

Question. What are the technological breakthroughs of the past year and what further developments are needed for the program to be on track 5 years from now?

Answer. In mapping, our 5 year goal is the creation of physical maps covering continuous stretches of DNA of between one to two million base pairs in size. Until recently, the length of continuous DNA that could readily be mapped was about one-tenth of that size. In the past year, work in the laboratory of Dr. David Schlessinger at the Washington University in St. Louis has led to maps of continuous regions of the human X chromosome of the desired size, thus demonstrating that our 5 year mapping goals are achievable.

In the sequencing field, important advances have also been made in the past year. The existing automated sequencers have now been perfected so that a number of laboratories report that they can produce 8,000 base pairs of raw sequence per day. With improvements in the capacity of the machines and their software, it is expected that this rate can be increased several fold in the near future. There is also promising research under way on projects that are novel, such as separation of bases by capillary gel electrophoresis and detection by mass spectroscopy. The results of this research will not be available for a few more years, but it is possible that one of these methods will be superior to the current machines.

REASSESSING THE 1 cM MAP GOAL

Question. Recent reports in the press have indicated that the program has already backed off from its initial goal of accomplishing a 1 centimorgan map in the next 5 years. Is this the case, and if so what is the new plan and will it mean the project will not be finished in the projected 15 years?

Answer. The human genome program has not changed its genetic mapping goal in any substantive way. All along, the genetic map has been seen as playing a dual role in the Human Genome Project. The first is as a tool for the identification and location of genes that can only be recognized by their effects, such as those that are associated with certain diseases. For this purpose, a three to five centimorgan map is generally considered to be of sufficient resolution. The second is as a tool to help assemble the physical map. Two years ago, a one centimorgan map was considered to be important to help order physically mapped units. Recently, however, physical mapping techniques have improved and it is now believed a two centimorgan genetic map may be adequate for physical mapping.

This refinement in the goal was based on the assessment of recent technical improvements in mapping. In the same way, we intend to frequently reassess and update the goals of the program in the light of technological improvements in order to keep the cost of the effort as low as possible. It would be a mistake to consider each redefinition of the goals as a failure of the program or a delay in finishing it.

THE NEED FOR MAPPING AND SEQUENCING MODEL ORGANISMS

Question. The mapping and sequencing of several model organisms is included in the goals of the NIH genome program. Why do you believe that the study of such model systems is needed to accomplish this project in humans?

Answer. The study of model organisms has been an integral part of the NIH research program for many years. The use of model organisms has allowed us to gain important insights into human biology by providing systems that can be easily manipulated experimentally and compared to the human, as well as by providing a test bed for methods and techniques that are later applied to the study of humans.

In the Human Genome Project, the mouse will be a particularly valuable model because the genetic crosses that are needed for detailed mapping, but which cannot be done with humans, can readily be accomplished in the mouse. A number of studies have already shown that there is considerable conservation of gene sequence and gene clustering between mouse and man. Therefore the mouse map will be used to help scientists predict what human genes map together and to predict the function of newly identified human genes. In other model systems, such as bacteria, yeast, worm, and fruit fly, where the genomes are much smaller and more easily analyzed, scientists will not only gain knowledge about the function of individual genes and the structure of the genome of an important microorganism but will also test strategies they will need to use for mapping and sequencing the human genome.

THE NEED FOR A MULTIDISCIPLINARY APPROACH

Question. Achieving the goals of the genome project will require input from many different scientific disciplines. How does the program intend to address the need for a multidisciplinary approach?

Answer. There are two ways in which the multidisciplinary research needs of this program will be met. The first is through the Human Genome Research Centers, where a group of 5 to 15 scientists from a variety of research fields will work together to address a major research goal of the program.

The second method will be the training program which will emphasize multidisciplinary training, both at the predoctoral and postdoctoral levels.

SPECIFICS ABOUT THE ETHICS PROGRAM

Question. You have stated that you intend to devote 3% of your budget to studies on ethical and legal issues related to the genome project. Can you be more specific about what types of activities you plan to support in this area? What are some of the questions that you think are most important to address? Will this simply be an academic discussion or will the public be involved?

Answer. The successful accumulation of genomic information will require that we as a society be prepared to know how to use that information sensibly for the benefit of individuals and society as a whole. The goal of our ethics program is to define the problems that may arise and develop useful safeguards, as well as provide information to the public. We have organized a joint NIH/DOE working group on ethics, legal, and social issues to provide us with advice on how best to achieve this goal. This group is now working on defining the research agenda and has recently held a workshop that brought together a number of interested scientists and non-scientists to discuss priorities in this area and to help plan a series of town meetings that we intend to sponsor in 1991 to solicit public input on these issues.

We also plan to support conferences that will bring geneticists together with lawyers, bioethicists, sociologists, theologians, representatives from labor, and the insurance industry to discuss the impact of the information generated by the Human Genome Project on their particular areas.

Additionally, we will support research training of scholars and scientists who wish to study ethical, legal, and social implications of the genome project.

INVOLVEMENT OF MINORITY INVESTIGATORS

Question. Tell me how you propose to increase the involvement of minority investigators in the human genome project?

Answer. The NCHGR is anxious to have minority students and faculty participate in our research and training programs.

We recently sent letters to all NCHGR grantees advising them of the Minority Supplement Program established by the NIH and encouraging them to apply for supplements to support minority students and faculty interested in genomic research. We are preparing to send a similar letter to the program directors of the Minority Biomedical Research Support grants and the Minority Access to Research Career grants. Additionally, we plan to fund eight students under the Minority High School Student Research Apprentice Program sponsored by the Division of Research Resources. Through this program we hope to kindle an interest in genomic research in those very young people needed to see this Project through to completion.

Furthermore, we are currently having discussions with leaders of the Association for Minority Health Professional Schools (AMHPS) and the director of the Research Centers in Minority Institutions (RCMI) program about sponsoring a scientific conference involving scientists from minority schools to discuss the Human Genome Project and how these schools can participate.

WHY THE ENTIRE GENOME APPROACH?

Question. Many scientists believe that the genome project should be approached by first targeting the study of disease genes or other interesting genes. Why have you not chosen this approach for the project and what is the advantage of the approach you have chosen? How are the results of the genome project being communicated to scientists who are more directly studying human disease? Are these scientists participating in the project?

Answer. We have chosen to approach the project from the point of view of the entire genome because we believe that this is the only way in which we will accomplish the whole project. The gene by gene approach would lead to a loss of momentum because we would become prematurely engaged in the analysis of the biology of an interesting region and because we would be likely to completely miss regions that will turn out to be extremely important but which do not appear to be interesting at this time. While I encourage genome scientists to begin to analyze interesting regions as they map and sequence them, I believe that we would miss important information in the unexpressed DNA if we concentrated only on the expressed regions.

The results of the genome project are being communicated to other scientists in many ways, including the normal channels for the distribution of scientific results: publications, scientific meetings, and databases. We are also looking to improve existing databases and develop any new ones that will be necessary to make the products of the genome project readily available to those scientists who need and want them.

Many human geneticists are involved in the project through individual research grants and we expect more to be involved through the research centers and research training programs. While we do not intend to fund searches for individual genes, we do encourage projects that involve improvement in the technology available for identifying genes of importance. Human geneticists are actively involved on all of the advisory committees, councils, and review panels that NIH uses in planning and effecting the genome project. We have developed close liaison with the American Society for Human Genetics, especially their committee on the human genome.

THE NUMBER OF HIGH QUALITY CENTER APPLICATIONS

Question. Dr. Watson, I see you plan to fund nine research center grants in FY 1991 compared to three in FY 1990. That is a large increase. Will you be able to get enough applications of high quality?

Answer. I am confident that we will. We anticipate about a dozen applications for FY 1990, all from highly qualified groups. Since we have only budgeted for three centers this year, there will be carry over applications from FY 1990 that can be funded in FY 1991. In addition, we are already aware of several new applications that will be submitted for funding in FY 1991.

COMMERCIAL DEVELOPMENT OF INVENTIONS

Question. How will you make sure that the inventions coming out of this program are developed commercially as effectively as possible?

Answer. On February 22, 1990, I met with the Industrial Biotechnology Association (IBA) at their annual meeting. We are anxious to improve communications with all the interested industrial groups and develop a plan for how we can assist them. We are currently recruiting for an individual who will specialize in this area to join our staff. The role of this individual will be to make sure that industry has rapid access to our information and to make us aware of industry needs and any barriers that are impeding technology transfer so that we can deal with them.

COORDINATION WITH OTHER INSTITUTES AT NIH

Question. How are you coordinating your project with the other Institutes at NIH which are pursuing the isolation and analysis of specific disease genes?

Answer. At the NIH we have a coordinating committee for this purpose. We provide information regularly to the other Institutes, my staff has visited a number of the Institutes and their Advisory Councils and conversely they have sent representatives to our Advisory Committee meetings. In organizing conferences we generally include individuals who are likely to use the data and technology produced by the genome project and are grantees of other Institutes.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

Question. Dr. Watson, I understand it is estimated that the Human Genome Project, when fully operational, will cost $200,000,000 per year. The fiscal 1991 budget requests an increase of over 80% for this project, but the NIH as a whole receives less than a 4% increase. In lay terms, how do I respond to the people of Pennsylvania when they ask me why we are spending so much on this single project?

Answer. I believe that the Human Genome Project represents an extraordinary opportunity to make a significant advance in our understanding of human biology. Genetics has been a significant component of the research programs of many, if not all, of the Institutes at NIH for years, increasingly so over the past decade. One aspect of this work has been the mapping and sequencing of individual genes. Thus, the NIH has been supporting genomic analysis, but in a necessarily piecemeal manner. In contrast, the genome project will accomplish the characterization of the entire genome of the human and other organisms in a systematic manner. I believe that this approach will make this significant information resource available to the scientific community much more rapidly, much more completely, and in a much more cost-effective manner than would otherwise occur. In turn, this will aid the biomedical and biotechnological research communities in their attempts to improve the health status of the U.S. public and the economic status of the U.S. biotechnology, pharmaceutical, and other industries.

With regard to the increase in the budget for the NIH component of the Human Genome Project, this is a new program that needs to grow to a mature size rapidly in order to be completed within the time frame proposed. The rate of progress in scientific achievement that we have witnessed in the past 2 years is evidence that the program can usefully sustain this rate of growth. For example, scientists have recently shown that they can construct overlapping sets of human DNA clones representing about 2 million base pairs of DNA. This is in contrast to the situation just 2 or 3 years ago, at which time the region that could be isolated in this way was only about 200,000 base pairs in size.

Question. When this project is completed, how will the data be used and how will it contribute to understanding and treating disease?

Answer. The ways to use information developed by the Human Genome Project will be myriad, limited only by the imagination of the scientific community. When finally interpreted, the genetic messages encoded within our DNA molecules will provide the ultimate answers to the chemical underpinnings of human existence. They will not only help us understand how we function as healthy human beings, but will also explain, at the chemical level, the role of genetic factors in a multitude of diseases such as cancer, Alzheimer's disease, and schizophrenia, that diminish the quality of the individual lives of so many millions of our people.

By knowing the structure of genes, we will be able to design and test, in an informed and targeted manner, a variety of new therapies. One particularly exciting possibility is targeted drug design, in which new medicines are planned at the chemical level based on their predicted interaction with the specific proteins that are affected in particular diseases. While the ability to do this will depend on research advances in the area of structural biology as well, genome data will be essential for rapid progress in this area.

NATIONAL LIBRARY OF MEDICINE

STATEMENT OF DR. DONALD LINDBERG, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Last, Dr. Lindberg, National Library of Medicine, we appreciate the efforts you pursued over the last year to increase the outreach of your services to world communities and the underserved areas of the country. We have talked about that before, and I am pleased to see your progress in those regards.

For fiscal year 1991 you are asking for $89.92 million, a 4.89-percent increase. Welcome.

Dr. LINDBERG. The mission of the National Library of Medicine is to acquire, organize and disseminate the biomedical information of the world for the benefit of the public health.

That has been quite well understood for 154 years, but things are changing fast. We are rapidly finding that we are truly in an information revolution and a computer age. To a great extent, NLM is at the center of those aspects that concern biomedicine.

I think some of the examples of the priority programs I mention to you will illustrate that for you.

During the last year we performed 5 million online searches; that is up 4.5 from the year before. There are 50 subset licenses to commercial and university clients. There are 17 overseas centers for MEDLARS services.

We are now using CD-ROM's, a new electronic form of the MEDLINE data base. In this case, they were developed with 10 private information vendors. We did it that way because marketing research was needed rather than basic research.

Senator HARKIN. What do you have on those?

Dr. LINDBERG. The CD-ROM's are magnetic recordings of the MEDLINE data base. They are on 5¼-inch disks which can be used on the little machine, very similar to the audio machines. With them the data base would be available on one's desk.

They are still somewhat expensive in that they are sold to institutions like libraries, medical schools, or partnerships. They are sold by commercial outfits to whom we lease the tapes—we guarantee the quality of them—and they are now present in 45 countries.

The information is really reaching the Third World and beyond, as well as the United States. The CD-ROM provides on-your-desk service to places in the world where we cannot get our services directly. This is in addition to the 5 million inquiries of the NLM online system.

NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

Another example of the new information age being upon us is the faith the Congress had in creating the National Center for Biotechnology Information 2 years ago. I should report to you that it's off and running and a great success. The brilliant new director of that group, Dr. David Lipman, is working extremely well with Dr. Watson and his colleagues and others around the country.

They have the mission to do research on the new information systems needed to handle this wealth of new sequence and mapping data, to be simple about it. There are lots of details to it, of course.

By way of a kind of breakthrough, I thought I would mention the thing that Dr. Lipman told me last week. One of the basic things one would assume would be done when any data is deposited in the genbank or the depository for sequence data, is to ask the question: Is what I have just put in identical with or like something that is already there? In other words, is it a discovery? Is it a real addition?

Now you would think, just as a bank would ring up your deposit and verify it against the account, that this would be automatically done, but it's not. It is not done automatically by any stretch of the imagination. It has to be requested. It is an overnight service. It takes hours on a big computer.

Last week Dr. Lipman and company found a new way to do it with a program they call BLAST, in which any sequence you specify can be compared with all the sequences—30 million I guess now if I am not mistaken, in 5 seconds. So while you hold your breath, the whole comparison is done.

We are very proud of that, but also knowing that with the progress Dr. Watson and his centers will make, there will be 1,000 times, maybe 1 million times as much data by the time his project finishes. So we have to keep working on the informatics as well.

AIDS INFORMATION SERVICES

In the AIDS area, the Congress required certain new information systems of us, and broadly these are successful. There are data bases such as AIDSline, AIDStrials, AIDSdrugs, and they are all running.

OUTREACH

Our top priority in the last year has been the outreach efforts as the chairman mentioned, and as recommended by the DeBakey panel as part of our long-range planning effort. The panel told us to be sure that American health care professionals are aware and capable of using the innovations and information systems that we are developing.

We should be prepared to provide health professionals with access but they have to meet us half way. We have to go out and be sure that they are informed and using the best systems that are available.

The panel urged us to work through the existing regional medical library network to initiate a new series of grants and to improve library access and information system grants, to continue the IAIMS programs, to train more health care professionals in computer systems, to create a kind of production line of new products and services, and to increase publicity of current products and services.

So we are doing those things to the best of our ability, adding to that the advice of the board of regents and the Secretary's office to make special efforts to be sure that rural citizens, minorities and the underserved populations do receive a special effort, and we are doing that.

TOXICOLOGY INFORMATION

In ending, I would just like to mention two other aspects in which the Library of Medicine is affected by the legislation and the Congress. We mounted this year, for the first time, a major new information system called toxicological release inventory or TRI. This contains some 300 chemicals from over 40,000 sites in the United States, which EPA has a legal mandate to collect data from the chemical producers and users.

They asked us to make this available to the public as the law required, and we have done this successfully.

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Last, NLM was also mentioned in another piece of legislation passed by the Congress, that which created the Agency for Health Care Policy and Research. In that legislation we were asked to make an agreement with the new administrator to handle the bioscientific literature of health care research and to create a new center at NLM for health care technology assessment information.

PREPARED STATEMENT

There are no funds connected with that bill, but we hope to work out an agreement or perhaps an interagency transfer of funds with the Agency for Health Care Policy and Research.

In closing, our request for fiscal year 1991 is $89,916,000. I would be pleased to answer any questions you may have.

[The statement follows:]

STATEMENT OF DR. DONALD LINDBERG

Mr. Chairman and distinguished members, it is both a privilege and a welcome opportunity to appear before you today. The services of the National Library of Medicine (NLM) and the unparalleled collections of health science information upon which they are based are essential to both biomedical research and the delivery of health care in this country. The Library's programs exploit the latest advances in technology and information science in order to ensure access to this information by medical scientists, educators, and health care practitioners.

FY 1989 saw important advances in a number of the Library's programs. Those I will highlight today include biotechnology information, AIDS, development of a Unified Medical Language System, and outreach activities.

Biotechnology Information

The creation of the National Center for Biotechnology Information (NCBI) in 1989 reflects the high priority of the Congress on developing new information technologies to help understand the molecular process that controls health and disease. The explosion of information relating to areas such as molecular biology, biochemistry and genetics, results in the need for sophisticated information resources to serve the biomedical community including NIH's Human Genome initiative.

During FY 1989, a multi-disciplinary research group of computer scientists, molecular biologists, biochemists, physicians and structural biologists was assembled to (1) build new databases and enhance existing ones that involve genomic information, (2) develop tools for information retrieval and analysis, and (3) ensure communication of the information to the scientific community. Much has been accomplished in a very short time.

The Center is developing the GenInfo database both to provide a core of biological information about DNA and protein structures and to link with more detailed information in other databases. Also, the Center is creating "software toolkits" to facilitate information retrieval. The first such toolkit, now being used to produce a computerized map of the E. coli genome, will serve as a prototype for analyzing more complex genomes. In addition, the Center sponsors meetings, workshops, and lecture series, and supports grants and postdoctoral training.

AIDS

The Health Omnibus Program Extension of 1988 that established the National Center for Biotechnology Information also called for the NLM to establish databanks of AIDS-related information. NLM now has a family of AIDS databases to provide access to diverse types of AIDS-related information, and an expanded and enhanced AIDS Bibliography.

The AIDSLINE bibliographic database developed in 1988 was expanded in 1989 and made accessible nationally via GRATEFUL MED, the microcomputer search package that allows users to search MEDLINE. NLM will continue to augment AIDSLINE by incorporating citations from other databases and abstracts of presentations from AIDS-related meetings.

Two new databases were quickly brought online in 1989; AIDSTRIALS, a database created in collaboration with NIAID that describes ongoing clinical trials; and AIDSDRUGS, the result of cooperation with NIAID and the Food and Drug Administration, which describes the agents being tested in those trials. The Library also continues to publish the monthly AIDS Bibliography through the Government Printing Office. A series of more specialized AIDS bibliographies on specific topics and for defined audiences will begin publication in 1990.

Coordination of AIDS-related information activities in the Public Health Service has been strengthened through the creation, in 1989, of a Panel on Information Services as part of the PHS Executive Task Force on AIDS. This Panel is co-chaired by the Director of the National AIDS Program Office and the Director of the NLM.

Unified Medical Language System

The purpose of the Unified Medical Language System (UMLS) is to develop a practical language system that will permit communication between the many and varied automated health information systems. A fundamental barrier to improved access to biomedical information has been the difference in terms used to describe similar concepts in different machine-readable files. The goal of the UMLS is not to impose a single biomedical vocabulary on all users and systems, but to make the myriad of classifications invisible to the user providing a single logical method to easily access a variety of biomedical information sources.

There was significant progress in developing the UMLS in FY 1989. The initial version of the "Metathesaurus," the central vocabulary component of the UMLS, has been developed. Meta-1, as the first version is called, will be available for distribution in mid-1990.

Among the priorities for the coming year will be the expansion of Metathesaurus' coverage of terminology related to the particular health problems under investigation by the newly created Agency for Health Care Policy and Research. NLM will be responding to its legislative mandate to work with this Agency on improving information support for health services research and policy development.

Outreach

As a result of concerns that many health professionals did not have ready and timely access to vital health information, Congress recently amended NLM's mission to add the function to "Publicize the availability of [its] products and services."

In response, the NLM Board of Regents convened a Planning Panel on Outreach. The Panel has formulated a plan to guide the Library's efforts to improve awareness of and access to its information services by American health professionals in all settings.

The Planning Panel, chaired by Dr. Michael DeBakey, issued a report in June 1989 recommending that NLM (1) utilize the Regional Medical Library (RML) network as a workforce in the field to bring NLM's products and services to the individual health professional, (2) ensure through grants and other mechanisms that local health science institutions have direct access to national biomedical information sources (3) expand its training fellowships and demonstration grants to satisfy the critical need for community-based health professionals trained in the use of modern computer and communications systems, and (4) develop new information products and services to enhance the utility of its present information resources.

The NLM is working with members of the RML network to promote availability and improve delivery of NLM's services to the Nation's health professionals, particularly in rural and underserved communities. One avenue being explored is utilizing health science libraries at historically black schools to specifically target minority information needs. In 1990, in an effort to reach rural communities NLM will fund a major outreach effort in New England and begin projects elsewhere in the country utilizing the RML network.

There have been significant improvements in online access to NLM's databases in 1989 and NLM's outreach effort includes a major expansion in FY 1990. GRATEFUL MED now provides access to more NLM databases. To date, more than 18,000 copies of GRATEFUL MED have been sold. Additionally the first Macintosh version of GRATEFUL MED was recently released. Its distribution in FY 1990 will allow access to an additional segment of the biomedical community.

In an effort to define user needs and further improve MEDLINE, a critical study was conducted to see how MEDLINE was utilized, particularly in the practicing physician setting. The results indicate the dramatic impact MEDLINE has had on decisions and actions of health professionals. Such data will be useful in developing databases and improving access methods to a broadening user community.

Also resulting in greater outreach will be the expanded program of "access grants" for community-based hospitals and strengthened support for research training, and fellowships. Resources will continue to be directed to promoting the use of existing NLM information systems and the Library will utilize the feedback to develop new and enhanced products and services.

These highlighted programs are only some of the Library's current initiatives. The following is a brief program by program summary of other progress in FY 1989:

In FY 1989, NLM's Library Operations component celebrated the 25th anniversary of the Medical Literature Analysis and Retrieval System (MEDLARS). From its beginning in 1964 as a batch system that pioneered the use of phototypsetting technology, MEDLARS has evolved into a powerful multi-purpose biomedical information system that last year responded to 4.6 million online inquiries, distributed authoritative machine-readable data to more than 80 organizations, and produced more than 100 publications. During FY 1989, the number of active online access codes increased almost 50 percent to more than 30,000. Nearly half of these codes are issued to individual health professionals and researchers. The dramatic increase in the numbers of individuals doing online searches of NLM's databases has been stimulated by the availability and enhancement of GRATEFUL MED.

In the Toxicology Information Program, NLM helped develop a portable, computerized workstation that allows those responding to chemical emergencies to obtain information easily and quickly from databases on a compact disk, or by accessing hundreds of relevant databases provided by NLM or other U.S. information sources.

In 1989, NLM added EPA's Toxic Release Inventory (TRI) on NLM's TOXNET system for online searching. TRI contains data on the release of specific hazardous chemicals into the environment by facilities producing and using those chemicals. As a result, this information is now more easily obtainable by the general public. EPA and the Agency for Toxic Substances and Disease Registry have asked NLM to add several additional databases dealing with the properties of hazardous chemicals on TOXNET.

Recent advances in computer graphics and optical disc technology now make it feasible to build collections of three-dimensional, "living" medical images which can be rotated, examined from any angle, dissected and reassembled on the computer screen in ways which mimic the actual physical body parts; surgery can be practiced on the computer before it is undertaken on an actual patient. Researchers in NLM's Lister Hill Center are coordinating a "Visible Human" project to create a collection of three dimensional digital images representing the complete human body with all of its complex internal organs and body systems. The computer images will provide a powerful tool for teaching detailed human anatomy to health professions' students nationwide.

Our Extramural programs continue to serve as the unique Federal focal point for financial assistance to the nation's medical libraries and support of medical informatics research and research training. The authorization for Medical Library Assistance programs expires on September 30, 1990. These programs support projects conducted by medical libraries and other academic institutions. Projects range from the structured Regional Medical Library program, to the innovative research and training grants for medical informatics, to the development of IAIMS to improve access to health information.

In conclusion, the National Library of Medicine welcomes its expanded role in the areas of biotechnology and AIDS information management and we enthusiastically support the priority Congress has placed on promoting awareness of and accessibility to the Library's products and services. The basic services of the Library serve to close the loop between past and present research results and the future scientific discoveries in the field of biomedicine. The rapid and efficient dissemination of biomedical knowledge is essential to the continued progress being made in understanding human life and the pursuit of better health.

Mr. Chairman, the FY 1991 request for the National Library of Medicine is $89,916,000. I shall be pleased to answer any questions you may have.

BIOGRAPHY OF DR. DONALD LINDBERG

September 21, 1933. New York, New York

Education: A.B., Biology, Amherst College, magna cum laude, 1954; M.D., College of Physicians and Surgeons; Columbia University, 1958; Sc.D., Amherst College (hon. caus.) 1979; Sc.D., State University of New York, (hon. caus.) 1987.

Professional History: 1984-present, Director, National Library of Medicine; 1988-present, Adjunct Professor of Pathology, University of Maryland School of Medicine; 1971-1984, Director, Information Science Group, University of Missouri School of Medicine; 1976-1980, Director, Health Services Research Center with Special Emphasis Health Care Technology Center, University of Missouri-Columbia; 1972-1973, Consultant for Health Sciences to Vice President for Academic Affairs; 1969-1971, Professor and Chairman, Department of Information Science, University of Missouri School of Library and Information Science; 1970-1971, Staff, Vice President for Academic Affairs, University of Missouri; 1967-1970, Director, Regional Medical Program Information Systems; 1968-1970, Staff, Executive Director for Health Affairs, University of Missouri; 1962-1970, Director, Medical Center Computer Program, University of Missouri; 1967-1969, Director, Missouri Regional Automated Electrocardiography System; 1966-1969, Associate Professor of Pathology, University of Missouri School of Medicine; 1963-1966, Assistant Professor of Pathology University of Missouri School of Medicine; 1962-1963, Instructor in Pathology, University of Missouri School of Medicine; 1960-1963, Director, Diagnostic Microbiology Laboratory, University of Missouri Medical Center; 1960-1962, Resident Physician in Pathology, University of Missouri School of Medicine; 1959-1960, Assistant Resident in Pathology, Columbia-Presbyterian Medical Center; 1958-1960, Assistant in Pathology, Columbia University College of Physicians and Surgeons; 1958-1959, Intern in Pathology, Columbia-Presbyterian Medical Center; June 1955-Sept. 1955, June 1954-Sept. 1954, Research Assistant to Dr. O.E. Schotte, Amherst College.

Honors: Phi Beta Kappa; Simpson Fellow of Amherst College (1954-1955); Markle Scholar in Academic Medicine (1964-1969); Distinguished Practitioner in Medicine, National Academies of Practice in Medicine (1983); Member, Institute of Medicine, National Academy of Sciences (1985); Fellow, American College of Medical Informatics (1985); Surgeon General's Medallion (1989); Nathan Davis Award for Outstanding Member of Executiv Branch in Career Public Service (Federal Government) (1989); Walter C. Alvarez Memorial Award, American Medical Writers Association (1989).

Professional Memberships: Sigma Xi; American Society of Clinical Pathologists; College of American Pathologists (Telecommunication Network Committee, Committee on Emerging Technology); Missouri State Medical Association; American Association for Advancement of Science; American College of Medical Informatics; Association for Computing Machines (SIGBIO); Salutis Unitas; American Association for Medical Systems and Informatics, Board of Directors; Symposium on Computer Applications in Medical Care, Board of Directors; National Board of Medical Examiners, Board Member; Washington Society for the History of Medicine; Editor, Information Methods in Medicine, Lecture Notes in Medical Informatics, and Journal of Medical Systems; National Academy of Practice in Medicine Distinguished Practitioner; Computer Science and Engineering Board, National Academy of Sciences (1971-1974); U.S. Representative to International Medical Informatics Association, and Trustee (1975-1984); Board of Health Sciences Policy, Institute of Medicine; President, American Medical Informatics Association (1988-present).

Dr. Lindberg is the author of 4 books and more than 150 articles, reports, and chapters of monographs.

BIOTECHNOLOGY INFORMATION

Senator **Harkin**. I will start with you since we are here then, Dr. Lindberg.

Since you are going to be charged, as you say, with the responsibility for cataloging the work done by the genome project, it seems to me that this is going to place quite a burden on the library.

Is this going to require more of us? Are you prepared for that? To my untrained ear, it sounds like you are going to need quite a bit more in terms of personnel, computer access or the computers themselves.

Dr. **Lindberg**. The authorizing legislation authorized $10 million and the appropriations included $8 million, so we got off to a good start, and NIH was able to allow us to add 12 FTE's. I think we, borrowing from other divisions, are actually up to about 18 at this point.

The quality of the people is probably more important than the numbers. This is not a pick and shovel kind of operation, and I am pleased to say that Dr. Lipman is recruiting, so far as I can see, the very best young scientists in the world. There is a steady stream of superb M.D./Ph.D.'s in molecular biology, computer science and medicine who seem to be flocking to that Center right at the moment.

So I think what he might lack in numbers he is making up for in extremely high quality. We think we will be able to fully meet the challenges and look forward to them.

OUTREACH

Senator **Harkin**. On the outreach to rural areas and small communities, is it true that you had a 50-percent increase in subscriptions to the MEDLARS?

Dr. **Lindberg**. From fiscal year 1988 to 1989, we had a 50-percent increase. Actually, in the last 12 months we have had closer to a 70-percent increase. So all of that is holding up, largely due to Grateful Med, which is a computer program that doctors can use on their office IBM PC's or now Apple machines. That seems to be very well received.

But we want to make sure that the regional medical library people get a feel for what is out there, to instruct them to be sure that those who are holding back also know about it.

Senator **Harkin**. Thank you very much, Doctor.

Dr. **Lindberg**. If I can continue the 70 percent a year growth, I will be pleased.

STAFFING FOR NATIONAL CENTER FOR HUMAN GENOME

Senator **Harkin**. Dr. Watson, your new center was not officially created until the President signed the fiscal year 1990 appropriations bill last November 21. I understand you have received support services for the preparation of your budgets and other activities from the National Institute of General Medical Sciences.

Are you now fully staffed to provide all of the services for yourself?

Dr. **Watson**. Yes; we are still seeking to add several more necessary people to reach our ceiling of 30 FTE's, but I am very pleased to say I think we have a superb staff and we show NIH off at its best.

TIMEFRAME FOR HUMAN GENOME PROJECT

Senator **Harkin**. A little bit earlier today I kept asking the question: Can we collapse this timeframe for the human genome project?

Dr. **Watson**. Maybe a couple of years if we are very lucky.

Senator **Harkin**. You mean a couple of years from 10 or a couple of years from 15?

Dr. **Watson**. A couple of years from 15, but it really depends on when you start counting. I like to count from fiscal year 1991. Let me go back and explain why I seem such a pessimist.

When the project was first proposed about 5 years ago, it was really a $30 billion project. That is really bigger than anyone ever thought would get off the ground. It was opposed by a lot of people because the feeling was that, in order to accomplish the project in a reasonable amount of time about 20,000 people per year were needed and the biomedical community did not have them available.

When it was taken up by several committees at the National Research Council and the Office of Technology Assessment, points were that the technology and the efficiency could improve by a factor of 10, and that would reduce the cost to roughly $3 billion, and we could probably do it over a period of about 15 years.

Now, that proposal was 15 years of spending $200 million per year and we are just getting up to that point. If you take what is proposed in our budget for fiscal year 1991 together with DOE, it is approximately $156 million.

In terms of the money allocated to the project, the project effectively begins in fiscal year 1991. We have spent a little bit in startup costs, but what we are really trying to do over the first 5 years is two major things.

One is to get very good maps of the chromosomes. These maps are useful for the people who are trying to find the disease genes. For example, an even better map might help identify the gene determining Huntington's disease, so first, we are going to get very good maps.

The second thing is substantial support for pilot projects, with the aim of reducing the cost of sequencing from the current $3 to $5 a base pair down to 50 cents a base pair. We have received four applications from people who are very serious sequencers and who have different methodologies they are proposing. I am pretty confident that within 5 years we will get the cost down.

Currently, we are getting the cost down by moving from human beings to machines. So effectively, we can carry out the project without diverting a large number of well-trained people from medical science to the genome project.

I think we can carry out the genome project without creating a great shortage of people in other biological disciplines, if we move to a machine-based effort. That is what we really want to do.

The other reason why we want to move to the machine-based sequencing is that the process the way it is currently performed, will be incredibly boring. So intelligent people will not want to do it, and without intelligent people, well, you can imagine the accuracy of such a process.

So what we want to do is get the project in the hands of very bright people, because they are the ones who are going to keep the cost down and get the project done in a reasonable period of time. To get the very bright people involved, you are going to have to create a situation where the data will flow off fairly fast and so it will be interesting to them.

The machines' technology is coming along. When we first talked about the project seriously 3 years ago, the sequencing machines were not there, only the prototypes were available. We had a meeting a few months ago at Wolf Trap, near Washington, DC, for the first time I began to see the sequence data flowing.

I am not really worried, I think it can be done.

And as far as the mapping goal, 5 years ago that looked like it was going to be difficult to achieve also.

But because of the work done at Washington University in Dr. Maynard Olson's laboratory, it is now possible to isolate rather big pieces of human DNA as parts of tiny yeast artificial chromosomes called YAC's. We can get these big fragments of DNA and actually line them up in order. This process was first shown at a meeting in Houston in December. There is a group now in Paris which is doing very good work with the YAC's also.

Senator **Harkin**. Where?

Dr. **Watson**. In Paris.

Senator **Harkin**. Also Japan?

Dr. **Watson**. No; not in Japan. I think the best work on YAC's is either done in St. Louis or in Paris.

INTERNATIONAL COLLABORATION

Senator **Harkin**. I understand the British, the Belgians, the Japanese, and Russians, all have human genome mapping and sequencing efforts underway?

Dr. **Watson**. Yes; they do, but they are not doing this new technology. The yeast artificial chromosomes, where you can get these big pieces of human DNA, that was a technique invented here in the United States about 3 years ago, which is now being developed. It is going to be passed throughout the world and the first place it has been passed is to the French. They are essentially using our procedures.

So I think we can get the maps done in 5 years, and I think we can get the sequences done in the following 10 years.

Senator **Harkin**. Maybe I lack a little bit of the scientific knowledge, if you are doing this mapping, and you have other countries who are doing it, are we coordinating efforts?

Dr. **Watson**. Yes.

Senator **Harkin**. Can the map be segmented?

Dr. **Watson**. Yes; you can because there are 24 different chromosomes.

Senator **Harkin**. Then why do we not cooperatively work on it?

Dr. **Watson**. Yes; I had proposed that and people said that I was silly.

Senator **Harkin**. Said what?

Dr. **Watson**. I was silly, you know, unrealistic. The reason is because there are lots of gene mappers out there and many people are now working on every individual chromosome. So how do you decide that a given country, say France, should do chromosome 8?

Now, I think it is going to pass to something like that because most of the people who are doing genetic maps now are doing it to find their own specific disease gene. They want to find Huntington's disease. They are not really doing it because they like maps per se. They are doing it for a very important purpose of finding a disease gene.

We have to find a second group of people who just like to make maps because they are maps, and they tend to be chemists or nucleic acid chemists. They are a different breed.

So we are developing this breed, and I am confident that, sparked from the work which is being done in St. Louis, it is going to spread throughout the country, and with that, spread throughout the world.

An important aspect of getting the job done fast is to get other major industrial nations in the world joining in on the project.

Senator **Harkin**. Is that being done?

Dr. **Watson**. Yes; we are trying to coordinate international collaboration.

Senator **Harkin**. It seems to me that this would almost call for a very high level meeting sponsored by the heads of the governments of the different countries, to agree upon what segments they are going to take.

Dr. **Watson**. Yes; what we have essentially done is set up a private organization called the Human Genome Organization [HUGO]. The startup is being funded by private sources—that is foundations.

The first real grant to HUGO has come from the United Kingdom, it has already been made from the Wellcome Trust, to get HUGO going in Europe. We have every confidence of an even larger grant coming from the United States.

Now as to whether we should get the heads of state together, my hope is that at the meeting of the seven major leaders in the summer of 1991, we will have prepared the ground so that the countries can come together and make that agreement.

About 2 weeks ago I spoke in Switzerland to Dr. Herbert Curien, the French science minister, who strongly backs the project. I think we can get the project before the heads of state. I have spoken to Dr. Allan Bromley and Dr. James Wyngaarden and that is our goal.

I think if we tried to do it this year we would not have done enough homework. When you get the heads of state together, you want the agreement already made so they can sign it, effectively. We have a lot of homework still to do before the signing process. But it is one of my major objectives. International collaboration will certainly get the project done faster and it will also reduce the cost to the United States. International collaboration will also do away with any problems of releasing data immediately to those who did not contribute financially.

So I am spending a great deal of my own time trying to work to see that all the major nations join in the project.

Senator **Harkin**. Are you able to spend enough time on this project? Do you feel comfortable——

Dr. **Watson**. Well, I first said I would spend 2 days, and at the time I thought I could have 5 days of peace in Cold Spring Harbor, but thanks to the fax machine I am reached at every moment. So I am really working on the project 7 days a week.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator **Harkin**. I understand. I still want to follow this closely. I have some other questions I might want to submit in writing if you could help us with that.

[The following questions were not asked at the hearing, but were submitted to the Library for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

OUTREACH

Question. For a number of years the Committee has been urging the Library to increase its outreach efforts, particularly in rural communities. I understand that the Library has had a 50 percent increase in subscriptions to the MEDLARS and GRATEFUL MED systems, and that the largest percentage of these new subscribers are physicians.

Could you give the Committee an update on your efforts to increase outreach to health care practitioners across the country?

Answer. In an effort to develop an outreach program aimed at alerting health professionals to NLM's resources, the NLM Board of Regents convened a Planning Panel on Outreach. The Panel, chaired by Dr. Michael E. DeBakey, advised NLM on how to make its information services better known within the health sciences community. The Panel's Outreach report now serves as a basis for the Library's outreach program.

NLM's outreach program is based upon the enhancement of ongoing programs such as the Regional Medical Library (RML) Network, Integrated Academic Information Management Systems (IAIMS) Grants, Resource Grants, Training Grants, and the improvement of services such as GRATEFUL MED. Congress has provided approximately $3.8 million in the FY 1990 budget for outreach.

In FY 1990, NLM is awarding RML enhancement projects designed to make minority and rural health professionals aware of available information resources, and will recompete the RML contracts, incorporating more outreach responsibilities. Underlying the Outreach report recommendations is the belief that direct access to NLM's products and services can, to a significant extent, compensate for the relatively poor status of traditional channels of health-related communication in rural and other underserved communities populated by minority and other low-income groups, as well as improving the delivery of health care in better-served areas. Working in collaboration with the member libraries of the Regional Medical Library Network, including health science libraries at historically black schools, and with other governmental and community-based organizations, demonstrations testing alternative strategies for improving information access will be put in place. There are ongoing RML outreach projects to health professionals in rural areas of West Virginia, Mississippi, Alaska, Oregon, Washington, Montana, and Idaho. New RML enhancement projects have just been awarded for outreach activities to health professionals serving in the Indian Health Service in Oklahoma, North Dakota and South Dakota and to rural health professionals in Western Massachusetts, Southern Iowa, Southern New York State, and Western Maryland.

NLM is also collaborating with the University of Texas, San Antonio, to provide experimental flat-rate access to NLM's databases for rural health practitioners serving predominantly Hispanic populations. A medical librarian will be traveling throughout the lower Rio Grande Valley to introduce these health professionals to the use of GRATEFUL MED.

NLM will also provide additional resources for Resource Access Grants and Training Grants in FY 1990. Access Grants are directed primarily to small and medium-sized hospital libraries, the institutions to which health-care professionals turn most often for access to biomedical publications and electronic bibliographic databases. An estimated fifteen Access Grants during FY 1990 will be started with the Congressional increase. The Outreach Panel found that there are not adequate numbers of persons in the biomedical fields who have had training in the use of modern computer and communications systems. The Congressional increase provides increased support for training grants.

To accomplish its mission to disseminate information for the advancement of medical science and improvement of public health, NLM is promoting the use of its current products and services. In FY 1989, the Library trained graduate students in the biological sciences to demonstrate GRATEFUL MED and NLM databases to their colleagues at the summer scientific conferences sponsored by FASEB. This program was very successful and will be expanded in FY 1990. NLM and two of the RMLs also undertook expanded exhibit schedules with NLM targeting national meetings of professional associations and the RMLs concentrating on local, state, and regional meetings. The Library also used direct mailings to selected groups to publicize the availability of GRATEFUL MED. In FY 1989, the number of active codes for use of NLM's system again increased by almost 50 percent to a total of 30,993. Most of the new users were individual health professionals. In FY 1989, more than 1.6 million inter-library loan requests were entered in DOCLINE and 92% were filled. This summer, NLM plans to test link between GRATEFUL MED and DOCLINE that would allow health professionals to request copies of the articles they identify in MEDLINE via GRATEFUL MED.

NLM's goals in FY 1991 are to: restructure the RML network along the Northeast corridor and award new RML contracts with greatly expanded outreach responsibilities; increase the number of Resource Access Grants and to bring the IAIMS program closer to its originally envisioned level of support; increase the number of Training Grants and fellowships; expand evaluation, publicity and promotion efforts; and develop a production line of new products and services.

We believe that we have made a good start already, and that eventually, our outreach efforts can put NLM's vast store of knowledge into the hands of every health care practitioner in the country.

Question. What percentage of health care practitioners are served by the National Library of Medicine each year?

Answer. Available data indicates that there are more than 462,000 physicians primarily engaged in patient care, 1,500,000 nurses, and 158,000 dentists nation-wide. Because NLM serves health care practitioners both directly and through other organizations, (the health sciences libraries in the Regional Medical Library Network and the commercial database vendors and institutions which provide online access to NLM databases), we cannot provide a good estimate of the total percentage of these practitioners currently reached by the Library's services. We do know that virtually all practitioners affiliated with medical schools have ready access to NLM's services and that well over half of the 135,000 hospital-based physicians and the 1,500,000 nurses could obtain NLM services through their hospital libraries. The most difficult to reach practitioners are those unaffiliated with professional schools or hospitals, such as dentists.

We believe that the dramatic increase in the utilization of GRATEFUL MED indicates that greater numbers of health practitioners are being served by NLM. In comparison with last year at this time, there has been nearly a 70% increase in the number of such users, most of whom are health care practitioners.

However, in order to assess our progress in reaching additional practitioners, one of the key components of NLM's outreach strategy is the establishment of good baseline data on current individual health professionals' use of NLM services. We plan to be able to provide better answers to questions like this one in the future.

Question. In your professional judgement, what additional funding would be necessary for fiscal year 1991 to continue the momentum of expanding outreach to rural areas?

Answer. The fiscal year 1991 budget request includes $3.9 million for outreach, an increase of 2.6 percent from the fiscal year 1990 level. The Outreach report called for a $35.5 million funding level for outreach activities in fiscal year 1991. This would provide enhancements for the RML network, Resource Access Grants, Training Grants, publicity and new products and services. Also included in the level recommended by the Outreach report are resources to support an increased number of institutional models through the IAIMS program. In my judgement, the $35.5 million level of funding recommended by the Outreach report would be the ideal to continue the momentum of expanding outreach to rural areas.

CIRCUIT RIDER

Question. I understand that at least one of your regional libraries has a "circuit rider" who travels throughout the service area giving talks and demonstrations to small community health personnel on library services.

Should this concept be expanded especially for underserved areas of the country?

Answer. For many years, "circuit rider" librarians have been employed in various parts of the country to provide actual library services in community hospitals that do not have resident library staff. Recently, a similar approach has been tried to introduce rural practitioners to the services they can obtain from NLM and the Regional Medical Library Network. In the RML project in the Pacific Northwest and another recent project in the Rio Grande Valley, librarians travel to small communities to describe and demonstrate online and document delivery services available to local practitioners. In 1990, NLM will be evaluating this "travelling librarian" approach to determine if the concept should be expanded.

CATALOGING THE HUMAN GENOME RESEARCH FINDINGS

Question. Dr. Lindberg, as you know the Human Genome effort is attempting to map and sequence the 3 billion genetic sub-particles. Currently, 3 million of these are being identified each year and within 5 years, it is projected that 30 million will be identified. Your job, of course, will be to catalog these in a systematic way so that they can be accessed by the research and health care community.

Are you adequately prepared to meet this challenge?

Answer. The Center considers it crucial to build a sound data management architecture for the task ahead. Therefore, a high priority has been given to the design of a database system that can accommodate input from a variety of sources, including direct author submission, the journal literature, and eventually directly from automated sequencing machines. The sequence database project at the Center, termed the GenInfo Backbone, has as a design goal, modularizing the data input, data review, annotation, and distribution components thereby reducing the complexity of building a biological information resource. The project has gone from the design to the implementation stage and it is expected that the current system could handle rates of data entry in excess of the 30 million per year projected in five years. The increased volume of data will likely be due to the submission of longer stretches of DNA resulting from the use of automated sequencing machines. Furthermore, this class of submissions is expected to occur through automatic means, such as direct submission by national networks in a format that requires less manual processing. Thus, the problem of the volume of data does not linearly scale with the number of new bases sequenced each year but is more directly related to the number of separate submissions. As a result, the anticipated increased volume of sequences will result in marginally increased costs.

PAPERWORK REDUCTION ACT REAUTHORIZATION

Question. I understand that a bill has been introduced in the House to reauthorize the Paperwork Reduction Act. This bill has been strongly opposed by the American Library Association. I also understand that language included in the House bill severely affects your ability to charge for your services.

Could you speak to the House reauthorization legislation and tell the Committee about the features of this bill that are being opposed by the American Library Association?

Answer. H.R. 3695 at section 103(c)(2)(D) and (E) contains restrictive provisions governing the dissemination of Federal information by government agencies. The American Library Association has adopted a resolution expressing its objections to these provisions which they believe will have an adverse impact on the dissemination of government information to the public. They oppose the restrictive factors found at (E) that are required to be considered by an agency in determining how to carry out its public information dissemination functions. They believe these factors denigrate the role of the government agency and elevate the role of the private sector at the expense of the public.

Additionally, H.R. 3695 at section 103(c)(2)(D) contains restrictive provisions that prohibit Federal agencies from exercising controls over government data redisseminated by the public, prohibit charging fees for redistributed data, and mandate "marginal costing" for products. When applied to databases such as NLM's MEDLARS, these provisions would restrict the NLM from entering licensing agreements with vendors for privately distributed MEDLARS databases. The agreements contain assurances that protect the quality and integrity of the databases. These quality assurances are vitally important to NLM's mission and to the protection of public health. In addition, our current agreements provide the means to recover access costs through reasonable fees. The NLM calculates fees across all products and services with access costs recovered in the aggregate. This ensures reasonable fees for all products and services, and full access cost recovery. The bill would prohibit charging fees for redistributed data, and would mandate "marginal costing" for products. This change would be in marked contrast with existing Congressional authorization and appropriation committee direction. Under the current policy, NLM with its appropriated funds pays the costs of creating the databases and the biomedical community incurs the costs, through fees, of accessing the databases. The potential impact for NLM could be elimination of its current cost recovery methods with a net loss of approximately $8 million in revenue a year.

Question. There have been some questions raised about whether you will continue to be able to maintain the high quality of your databases through your licensing arrangements. What is that all about?

Answer. The House Bill (H.R. 3695) to reauthorize the Paperwork Reduction Act would prohibit Federal agencies, including NLM, from imposing any conditions on the use and dissemination of the information products or services they distribute. NLM currently uses license arrangements which permit public access to NLM databases with the requirement that licensees maintain the currency of their database copies with corrections and updates supplied by the Library. Recipients of NLM data are also required to provide accurate representations to the public regarding the extent and nature of the NLM data they are providing. This ensures that members of the public who search NLM data on other systems will receive reasonably current and accurate data, incorporating the published information about significant errors, fraudulent data, and questioned results that NLM routinely adds to its previously indexed citations. Certain provisions in H.R. 3965 would prevent NLM from placing these quality assurance requirements on those who obtain and provide public access to NLM databases. As those who obtain and provide access to NLM databases incur some costs to update the databases with the new and corrected data supplied by NLM, the absence of a license agreement requiring them to do so could have the effect of reducing the quality and accuracy of the NLM data used by large segments of the public.

GENBANK DATABASE

Question. The National Center for Biotechnology Information was established in the past year. Does NLM manage or contribute to the GENBANK Database through this Center?

Answer. NLM has been a major contributor to the support of the GenBank database over the past several years. Last year's contribution, for example, was $350,000. An agreement has been reached with National Institute of General Medical Sciences (NIGMS), the Institute which has been administering the GenBank contract, which provides for future administrative control of GenBank by the National Center for Biotechnology Information (NCBI) after the current GenBank contract ends in September, 1992. This agreement was based on the congressional mandate of the NCBI to manage automated systems for disseminating knowledge in molecular biology and genetics and on the acknowledged expertise of the NCBI staff in database design and development. NLM has organized a transition team which includes representatives of the National Center for Human Genome Research and project officers from NIGMS to begin the technical and administrative planning for the next generation of molecular sequence databases. The major funding for GENBANK currently is included within the NIGMS appropriation.

GRANTS

Question. What are some of the major areas of emphasis that are funded through the grant mechanism?

Answer. NLM's extramural program provides a range of grants for research and development activities relating to the management, dissemination, and use of medical knowledge. These grants seek to improve biomedical communication and knowledge access essential in exploiting findings of health research in the advancement of medical education, practice and research. Some of the major areas of emphasis funded through these grant activities are:

Research Grant Program. This program offers grant support for a variety of scientific investigations and activities regarding health knowledge issues. There are three program areas: 1) Medical Informatics - includes studies of health knowledge representation, retrieval, and utilization in the context of advanced computer technology, such as work on an intelligent expert system for managing cancer therapy protocols; 2) Health Information Science - includes studies of bibliographic organization and retrieval of recorded biomedical knowledge, such as an evaluation of alternative retrieval capabilities for computerized medical bibliography; and 3) Biotechnology Information - includes investigations of more effective methodologies for organizing and analyzing vast amounts of data and information relating to molecular controls of life processes, such as a general pattern matching algorithm for biological sequences.

Training and Fellowships. NLM supports research training in the fields of medical informatics and biotechnology information. The general objective is to equip individuals to address fundamental issues which will advance the frontiers of the computer sciences for organizing, retrieving, and utilizing health knowledge. Regarding biotechnology information issues specifically, the appearance of new experimental methods has greatly increased the rate at which data are accumulating about the molecular control of life processes. Because of its volume and complexity, new ways must be found to represent and analyze this data using computerized techniques for storage, searching, and examination.

Publication Grant Program. Grants provide low-cost financial assistance for the preparation and publication of important scientific publications needed by U.S health professionals and which are not commercially viable. Supported studies include critical reviews and monographs on current and past developments in medical research and services, publications in health science librarianship and biomedical communications, and secondary literature tools in the health sciences, such as handbooks and other reference sources.

Resource Grants. Any public or private, non-profit health science institution or organization is eligible to apply for a Resource Grant for the purpose of improving information services to health science professionals. NLM currently has two programs of resource grants: 1) Information Access Grants for Health Science Libraries - these access grants are primarily intended for libraries of small- to medium-size community hospitals and to consortia of health-related libraries to facilitate access to and delivery of health science information via pathways employing the most up-to-date and effective computer and telecommunications technology available; and 2) Information Systems Grants for Health Science Institutions - these awards are available to health science academic institutions and to hospitals with significant teaching and research components. Their purpose is to utilize and improve the infrastructure for the transfer of health science information via technological means.

IAIMS Program. Integrated Academic Information Management Systems (IAIMS) use computer and communications networks to transform a health institution's various information bases into an integrated system. The goal is to link and relate the databases representing academic information, e.g., the published knowledge base and bibliographic records integrated into individual and institutional working information files, such as clinical, administrative, research, and educational databases. Institution-wide planning, model development, and implementation, and research related to IAIMS have been supported at some fifteen institutions since the program was established in 1983.

AIDS

Question. What is the Library's role in the battle against AIDS?

Answer. The Health Omnibus Program Extension of 1988 (P.L. 100-607) called for NLM to be involved in the establishment of a "databank on the results of research with respect to acquired immune deficiency syndrome conducted in the United States and other countries. NLM's efforts to meet this mandate have been focused on ensuring that those providing care to AIDS patients or working on AIDS research have easy access to the most up-to-date research results as well as information on the appropriate treatment, management and prevention of the disease. To this end, NLM develops, maintains, and enhances information products and services in the field of AIDS and publicizes these products and services to their intended audiences. As a result, NLM now has a number of AIDS databases which provide access to diverse types of AIDS-related information, and an expanded and enhanced monthly AIDS Bibliography.

The AIDSLINE bibliographic database, which contains over 25,000 references to the literature in this field actually pre-dates the legislation. Over the past year, AIDSLINE was expanded to include AIDS-related citations from two additional MEDLARS databases, HEALTH and CANCERLIT. AIDSLINE was also made accessible nationally via GRATEFUL MED, the microcomputer search package that allows users to search MEDLINE.

As part of the overall Public Health Service response to AIDS, NLM is participating in a joint project with the National Institute of Allergy and Infectious Diseases (NIAID), the Food and Drug Administration, and the Centers for Disease Control, to make information about AIDS-related clinical trials more readily available. This project is in response to the HOPE legislation's directive to "establish a data bank of information on clinical trials and treatments with respect to infection with the etiologic agent for acquired immune deficiency syndrome." In support of this, NLM has added two new databases, AIDSTRIALS and AIDSDRUGS, to its online system. AIDSTRIALS contains descriptions, including eligibility criteria, location, and contact information, of FDA approved clinical trials. The information about NIH sponsored trials is being provided by NIAID, while information about the privately sponsored trials is furnished by the FDA. AIDSDRUGS contains descriptions of the drugs being tested in these clinical trials.

The online Directory of Information Resources (DIRLINE) now contains descriptions of over 1,000 national organizations which are active in the AIDS area. These include voluntary organizations, information resources, educational organizations, foundations, and social services agencies. These records are supplied to NLM by the National AIDS Information Clearinghouse. In the future, we anticipate expanding this database with additional AIDS-related organizations. Health Hotlines, a brochure listing toll-free telephone numbers in a variety of health-related areas, contains many AIDS organizations. Health Hotlines is available free of charge from NLM and has been widely distributed.

Coordination of AIDS-related information activities in the Public Health Service has been strengthened through the creation, in 1989, of a Panel on Information Services as part of the PHS Executive Task Force on AIDS. This panel is co-chaired by the Director of the National AIDS Program Office and the Director of the NLM.

CHEMICAL EMERGENCIES

Question. Tell us about NLM's role in assisting in chemical emergencies.

Answer. The Library's TOXNET System has been used to respond to chemical emergencies by virtue of critically-needed data found in the Hazardous Substances Data Bank (HSDB). Within certain categories of the HSDB hierarchial structure resides information pertaining to the safety and handling of chemicals, hazards, fire-fighting information, preventive measures as well as emergency medical treatment data in cases where exposure to chemicals have occurred.

NLM, in conjunction with the Agency for Toxic Substances and Disease Registry (ATSDR), has developed a prototype microcomputer-based workstation designed for use by health professionals and related personnel in State and Federal agencies responding to hazardous chemical situations. This system, known as ANSWER, (an acronym for NLM/ATSDR Workstations for Emergency Response) is being field tested at 13 sites.

The workstation consists of databases on CD-ROM containing information on both hazard management and material management for over 2,600 chemicals, a database containing facts from previous chemical emergencies; a front-end telecommunications search package that provides a uniform query interface to over 500 remote databases; a specialized module for providing access to the National Weather Service online information databases; and a facsimile capability for sending and receiving information.

LITERATURE PRESERVATION

Question. Literature preservation has been an ongoing concern. What progress are you achieving?

Answer. NLM's preservation program has several components: preservation of the Library's own collection, preservation education and assistance for other U.S. health sciences libraries, promotion of the use of more permanent paper in the production of new biomedical literature, and research in the preservation uses of electronic technology. In FY 1989, the Library's microfilming contractor filmed 5.7 million pages of brittle books and journal volumes, including some journal issues borrowed from other U.S. and foreign libraries to fill in gaps in the NLM collection. Significant progress is being made in filming NLM's brittle volumes. NLM awarded the first two contracts under its National Preservation Plan to Yale and UCLA to provide partial funding of the preservation of important biomedical materials held by other U.S. health sciences libraries. The Library continues to pursue its permanent paper campaign with positive results. In 1989, NLM's Permanent Paper Task Force sent letters to all U.S. and some foreign publishers of journals indexed for MEDLINE and Index Medicus requesting information on their use of acid-free paper. As of 1990, all Index Medicus journals that reported to NLM that they are both printed on acid-free paper and including a notice to that effect are specially flagged in the List of Journals Indexed in Index Medicus, the List of Serials Indexed for Online Users, and SERLINE, NLM's online database of biomedical serial publications. In FY 1987, 12% of the Index Medicus journals were on acid-free paper and a mere 1% so indicated in their publication. Since the awareness campaign, the situation has shown significant improvement in 2 years, with some 83% of journals now on acid-free paper and 26% so indicating this in their publication.

AIDS INFORMATION SERVICE

Question. NLM has made an on-line database, AIDSLINE, which is accessible through the GRATEFUL MED software package, in response to a Congressional directive. AIDSLINE can be accessed by doctors from home or office for information on published research and clinical trials. In addition, NLM in collaboration with CDC has helped produce a hotline database, and in collaboration with FDA and NIAID a database on clinical trails information.

How much have the medical and research communities been accessing these databases? Geographically, has access been correlated strongly with the prevalence of AIDS cases?

Answer. In FY 1989, 19,000 searches of the three AIDS databases (AIDSLINE, AIDSTRIALS, and AIDSDRUGS) were conducted on the NLM system, accounting for about 1,780 hours of connect time. An additional 800 hours of AIDSLINE searching occurred on the systems of the International MEDLARS partners and commercial database vendors who lease the database. These figures do not include searches on AIDS-related topics conducted in the many other NLM databases that also cover segments of the AIDS literature. Use of the three AIDS databases is increasing as they become better known and as their coverage and search capabilities are expanded.

The pattern of access to the AIDS databases on the NLM system appears to correlate strongly with the geographic distribution of AIDS cases. The states that include the 10 metro-politan areas reporting the largest number of AIDS cases showed relatively heavy use of the databases, with California and New York accounting for 21% of the use.

Question. Are there particular sectors of the country in which AIDS-cases are known to be high that are not accessing these databases? If so, do you have any explanation for why this is the case?

Answer. Data from the NLM system would indicate that there is use of the AIDS databases in all regions of the country in which AIDS cases are known to be high.

Question. Are these databases accessible to doctors abroad? If not, do you plan to expand access to this sector?

Answer. AIDSLINE has been available to those abroad who search directly on the NLM system since October 1988. NLM began to lease AIDSLINE on tape to International MEDLARS Centers and information vendors in February 1989. To date, the database has been mounted on systems in West Germany and Switzerland.

Access to AIDSTRIALS and AIDSDRUGS will be extended to non-U.S. users in the spring of 1990. As with all its new databases, NLM allowed 6-8 months for refinement of documentation and correction of any hidden problems before beginning international distribution.

BIOTECHNOLOGY INFORMATION CENTER

Question. The National Center for Biotechnology Information is now a division of NLM. Among other things, this Center has been directed to coordinate a major initiative to improve database and resource information in biotechnology.

Give us a few examples of the types of biotechnology grants that your Center is supporting.

Answer. NLM currently supports sixteen projects as research and resource project grants. These are administered through its Extramural Programs. They result from two separately published Requests for Applications and the transfer of several biotechnology resource projects from another component of NIH. Examples of research project awards include the following:

At Stanford University, Professor Gio Wiederhold is creating a powerful workstation environment to enhance fluorescence activated cell sorting, an emerging biomedical research technology for molecular biology which also has relevance for clinical practice.

At the University of Colorado, Professor Gary Stormo is investigating powerful computer program approaches that identify new and interesting patterns in DNA sequences.

At the University of Pittsburgh, Professor Bruce Buchanan is designing a computer based assistant for molecular biologists, drawing upon advanced expert systems and concept learning methodologies in the computer sciences.

At Purdue University, Professor Lee Weith is investigating new computer algorithms for various complex analyses of nucleic acid and protein sequences based on relating large parallel processors to user friendly workstations.

At the Dana-Farber Cancer Institute in Boston, Dr. Temple Smith and his colleagues provide a valuable resource to the community of molecular biologists through their continuing development of computational methods for molecular genetic analysis. They make these methods generally available through a variety of collaborative and training relationships with other investigators and institutions.

Question. You indicated last year that your so-called "database of biotechnology databases" would be available in printed and computerized form during 1989. Is this directory database, intended to help researchers locate molecular biology information, as well as other resources such as clone libraries and tissue bank, now available?

Answer. The Directory of Biotechnology Information Resources (DBIR) was first made available to the public in electronic form in January 1989. It continues to be enlarged and refined, and now contains detailed descriptions of some 1,200 entities (databases, networks, collections and repositories, reference publications, etc.) in the area of biotechnology and molecular biology. The Specialized Information Services division of the NLM is responsible for the database and is currently evaluating the cost effectiveness of distributing this information in printed form.

Question. What improvements, if any, have been made in structuring, searching, and analyzing the data in existing biotechnology-related databases?

Answer. The National Center for Biotechnology Information (NCBI) has taken a fundamentally new approach to structuring data for sequence databases. It was considered essential to be able to capture the nucleotide and amino-acid sequence information as completely and as accurately as possible and to provide rapid access to users. The NCBI sequence database project is utilizing NLM's long experience in building biomedical databases and the expertise of biologically-trained indexers to capture sequence data from the over 3500 different journals that NLM regularly indexes. The data is being incorporated into a relational database system which permits maximum control over data consistency and integrity. The design of the system will also accommodate direct submissions of sequence data from authors which will become a more common mode of input as automated sequencing technology develops. Incorporation of earlier sequence data from the GenBank and Protein Identification Resource databases permits users an integrated view of all known reported sequences. The object-oriented design of the database permits the distribution of the data in various formats and modes. For example, software developers in the academic or in the commercial sectors could obtain frequent updates of the data in forms structured for their particular needs. Besides online access to the data, efficient distribution media such as CD-ROMs are planned.

The development of new algorithms for both faster and more accurate database searching is underway. The research group at the Center recently developed BLAST, a rapid search algorithm, which allows the comparison of 30,000,000 bases against a test sequence in five seconds. For searches where sensitivity, rather than speed, is the objective, THREE (a multiple sequence search algorithm) permits detection of significant biological relationships that were missed by existing methods.

Question. What other biotechnology information resource developments do you have planned?

Answer. Building upon the framework of the GenInfo backbone database, a software environment is being developed which will permit integrated access to sequence and supporting bibliographic data from MEDLINE. Because of the diversity of computer systems in place at users' sites, the access software is being designed for hardware-independence. The Center's initial focus will be on access via high-speed national networks. As a member of the national research network, Internet (NSFNet), the Center is connected to research institutions nationally and internationally through protocols that permit heterogeneous computers to communicate. These protocols will be used to develop access and retrieval software to the Center's sequence database, a biotechnology subset of the NLM's MEDLINE database, and to advanced sequence searching tools.

Question. Has the expanding backlog of biotechnology data improved during the past year? If not, what priority has this problem been given by your Center? What approaches are being used to deal with this backlog?

Answer. According to reports from the GenBank and PIR database producers, the backlog is decreasing. Extra funding for GenBank was specifically targeted for reducing the backlog which is expected to be cleared by the end of this fiscal year. The NLM assisted in the project by producing literature searches through the millions of records in MEDLINE to identify potential sequence articles that were not in the database. NLM is cooperating with the database builders by providing library facilities to locate the literature from the older and highly specialized journals. Internally, the Center recognizes the importance of keeping pace with the scientific literature and has therefore closely coupled the sequence database effort (GenInfo Backbone Database) with the standard processing flow that the NLM uses for building MEDLINE.

Question. Are you supporting any foreign biotechnology grants? If so, what kind of investigations are being done?

Answer. At the present time, NLM is not supporting any biotechnology grants in foreign institutions.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

HUMAN GENOME INFORMATION

Question. Dr. Lindberg, does the Library anticipate expanded responsibilities as a result of the research activities on the Human Genome project? If so, how much do you anticipate will be necessary to fund these new activities in FY 1991 and in the outyears?

Answer. The NLM does anticipate an expansion of its responsibilities due to the research related to the Human Genome project. There will undoubtedly be a steady increase in the amount of sequence data as the project establishes centers and as automated sequencing techniques become widespread. The amount of data, however, to be generated in FY 1991 and projected in the Genome project's five-year plan which the NLM will be responsible for collecting and disseminating, can, in our judgement, be accommodated by the systems we are designing and implementing without major increments in funding.

The increase in data generated will probably have its greatest impact initially at the laboratory level, before the data are ready to be disseminated publicly. Laboratory data management is an area that is funded and supported by the NIH Center for Human Genome Research and the NLM will assist as necessary to design systems that will transfer the laboratory data to public access databases.

Advances in sequencing technology that produce 2 orders of magnitude or greater increases in sequencing throughput could be expected in later stages of the Genome project, and this will likely require increased levels of funding for the support of public information resources. We anticipate that an additional impact of the Genome initiative on NLM responsibilities will be an increase in the size of the community desiring to access and use genome data.

The growth in the user community should not be substantial until these later phases of the Genome project when the community should expand from the current academic research base into a broader sample of academic disciplines, further into the biotechnology and pharmaceutical industries, and eventually into medical practice.

A factor which will require increased funds in the outyears is the contract for GenBank. It is planned that beginning September 1992 NLM's National Center for Biotechnology Information will have prime responsibility for awarding and managing the contract for GenBank, while utilizing participatory advice from relevant NIH Institutes and other Federal agencies. In that fiscal year, we would need about $5 million additional to cover the cost of GenBank. We expect that some increase in funding for the outyears will be necessary to keep pace with the data but such increases should not be substantial.

Question. Does the budget include additional funding to cover the FY 1991 costs?

Answer. The FY 1991 budget includes the necessary funding to cover the essential activities associated with expected gradual increase in data for the next year.

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Question. Do you anticipate additional workload as a result of the recently Congressionally established Agency for Health Care Policy and Research?

Answer. Yes. The legislation establishing the Agency for Health Care Policy and Research charges its Administrator to enter into an agreement with the Director of the National Library of Medicine to provide programs and services leading to more effective and timely dissemination of the results of health services research and to the development of new and improved methods for such information dissemination. The legislation specifically requires the establishment of an information center on health care technology assessment at NLM.

NLM's collection, its online services, and the Regional Medical Library Network provide an excellent platform for improving the dissemination of the results of health services research. To meet the responsibilities outlined in the legislation, however, the Library must establish a Health Services Research Information Center to coordinate all related NLM activities; increase its acquisitions of the technical report literature; improve bibliographic access to this report literature; expand coverage of related organizations in its online Directory of Information Resources Online (DIRLINE); create new indexes; and perform the research and development work necessary to develop new products and services, such as a new full-text database aimed at broad dissemination of practice guidelines. To insure appropriate use of existing services relevant to health services research and to obtain input on new services needed, NLM must develop an outreach strategy aimed specifically at those who perform health services research or use the resulting information.

These expanded activities can also be expected to increase demand for NLM's online and document delivery services and to require the provision of specialized reference service for questions dealing with health services research.

Question. If so, how much do you anticipate will be necessary to fund these new activities in FY 1991 and in the outyears? Does the budget include additional funding to cover the FY 1991 costs?

Answer. The FY 1991 budget does not include additional funding to cover the costs of responding to the new legislation, but we anticipate the transfer of funds to NLM from the Agency for Health Care Policy and Research in both FY 1990 and FY 1991. Beyond FY 1991, necessary funding should be included within the NLM appropriation.

Although an active and effective Health Services Research Information Center will eventually require an annual budget of $7,000,000 to $8,000,000 and 15-20 FTEs, we think that $2,000,000 and 7 FTEs represent an appropriate start-up level for FY 1991. This would allow NLM to establish the required Information Center and begin to acquire and index additional health services research reports, expand DIRLINE coverage of related organizations, publish special bibliographies and directories, establish an outreach program tailored to the health services research area, provide specialized reference service, respond to increased document delivery and online service demands, and pursue a research and development program for relevant products and services. Specific projects that would be undertaken include design and development of a full-text practice guidelines database linked to the literature references that provide the scientific basis for the guidelines; special GRATEFUL MED screens designed to facilitate inquiries in the field of health services research; special Unified Medical Language System (UMLS) enhancements and demonstration projects on problems that are the focus of practice guideline development; a research in progress database; and a database of descrptions of machine-readable data sets suitable for use in Health Sciences Research projects.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

JOURNAL SELECTION

Question. We understand that in evaluating medical and scientific journals for inclusion in Index Medicus, there are no formal criteria or standards which govern the review undertaken by the National Library of Medicine's Literature Selection Technical Review Committee. In fact, it appears that the only standards which have been enunciated are rather vague -- subject coverage, quality, purpose, and intended audience. Moreover, we understand that only a small percentage of the journals reviewed are accepted for indexing and that those which are rejected must wait two to four years before resubmission.

Can you indicate whether NLM plans to adopt formal standards so that publishers may be informed in advance of the criteria against which their journals will be judged?

Answer. NLM is attempting to address the concern about the availability of guidelines. The Library recently established a NIH chartered committee, the Literature Selection Technical Review Committee, to evaluate and recommend the journals to be indexed for MEDLINE and Index Medicus. The Committee had its first meeting in July 1988. The members decided it would be important for them to examine a number of journal titles covering a wide variety of subjects, publication styles, and the practices in different countries before developing and issuing guidelines. In the interim the Committee continued to use the principles that prior consultants had used, selecting serial publications they thought had substantive content of some enduring interest. Their review considers the potential value of the publication for the Library's primary audience, existing subject coverage, the quality of the original articles, and the purpose of the publication.

During its meetings the Committee has discussed many issues such as the necessity for English language abstracts in foreign language journals, the definition of scholarly, the emphasis to be given to peer reviewed journals, etc. A subcommittee has been appointed and after three meetings has drafted some general guidelines which the Committee will use in its next meeting, revise if necessary and issue later this year.

Question. If NLM has no such plans (or if it does, until such rules are published), will NLM consider issuing informal standards or guidelines so that a journal may increase its chances of receiving a favorable review?

Answer. NLM does plan to issue guidelines within one year. In the interim NLM does provide some guidance to editors and publishers. The one page of information sent to individuals inquiring about the review notes that the Committee attempts to judge the "potential value of the publications content for the users of the Library" and "considers subject coverage, quality of original articles, purpose and intended audience". The new guidelines will, however, be of a general nature. As is the case in the review of grant proposals, it is difficult to list specific criteria which if met, will guarantee acceptance and funding. NLM attempts to provide a broad coverage of biomedical subjects and geographical representation in MEDLINE and Index Medicus.

In addition, NLM attempts to index the journals that practitioners, researchers, and educators indicate are the most important and useful in their work. The Literature Selection Technical Review Committee is systematically reviewing the indexing coverage in each specialty by asking professional societies to rank the journals in their specialty and recommend which should be indexed. Titles ranked as very important that are not indexed are reviewed by the Committee for possible selection and titles not ranked as important that are indexed are reviewed for possible deselection.

A journal has several chances to be selected by the Literature Selection Technical Review Committee including as 1) a new title; 2) through the strong recommendation by professional societies during a subject review; and 3) a re-examination after an interval of time.

Question. We note as well that in declining to accept a journal for indexing, the rationale cited by NLM states that the journal is "less needed by the user community" than journals currently being indexed. Particularly given the absence of concrete standards, wouldn't it be appropriate to outline the precise reasons for denial so that the publisher has the opportunity to address NLM's specific concerns in a subsequent submission?

Answer. NLM estimates that there are about 14,000 biomedical journals currently being published. The Library indexes almost 3,000 and would require substantially more resources to increase this number appreciably. Last year the Literature Selection Technical Review Committee examined about 360 new titles and recommended about 60-80 for indexing with a priority high enough to be selected. Some titles are not recommended because the content is peripheral to bio-medicine and less needed by the primary user communities that MEDLARS serves or the contents do not have scientific merit. Other titles contain articles which are derivative literature and repeat information already well covered in the indexed literature.

NLM does not advise publishers on changes to make to their publications, assuming instead that the publishers have identified their purpose, audience, and content. The Committee is asked to review the journals to see if the title is in scope, meets the needs of the MEDLARS community, and has scientific merit, and if its contents are important enough to use public funds to index and provide access to it for users all over the United States and indeed throughout the world.

Question. Finally, given the lack of standards (and thus a publisher's inability to tailor his journal to meet NLM's demands), can you explain why a 2 to 4 year waiting period is necessary once a journal has been rejected?

Answer. The Literature Selection Technical Review Committee reviews about 360 new titles a year and two to three subject areas at each of its meetings. Publishers of new titles are anxious to have their journals reviewed as soon as possible and MEDLARS users are interested in having citations from excellent new journals available in MEDLINE and Index Medicus at the earliest date. If the Committee were to re-examine journal titles more frequently than after a two year interval, it could not maintain a timely review of new titles. Also a substantial portion of the Committee membership changes in two years, providing the publisher with a truly new second examination. Two year intervals are given to journals the Committee recommended for indexing with a priority score too low to be selected. Four year intervals are assigned to journals that the Committee recommended that the Library not index.

INFORMATION ACCESS

Question. The world is undergoing a biomedical and technological revolution, and it is becoming increasingly more important that researchers, practitioners, educators, and students have ready access to the latest information on the effectiveness of clinical treatments and new technologies. In your estimation, how well are we as a nation doing in terms of ensuring ready access to information for doctors, researchers, students, and educators?

Answer. Not well enough. Although there is a wealth of useful biomedical information in machine-readable form, we have not made sufficient progress in developing systems that allow health professionals and researchers to locate, retrieve, and integrate this information easily and effectively. NLM's Unified Medical Language System project is working to facilitate the design and implementation of such systems and the Integrated Academic Information Management Systems initiative is addressing other organizational and technological barriers to integrated access in institutional environments. A great deal of work remains to be done in both of these areas.

We also still have a very long way to go to bring currently available systems, such as GRATEFUL MED and MEDLINE, to the attention of all health professionals and researchers who would benefit from them. On the positive side, I would estimate that MEDLINE and other online databases are now readily available to all doctors, researchers, students, and educators affiliated with academic medical centers. A 1989 survey of graduating medical school students conducted by the Association of American Medical Colleges indicated that about 74% of the students had used MEDLINE during their years in medical school. This almost certainly represents a significant increase from even a few years ago. The increased student use is attributable to low cost access via local subsets of MEDLINE mounted on university computer systems, special student rates for direct online access to the NLM system, the GRATEFUL MED user-friendly search package, and a variety of commercially developed MEDLINE CD-ROM products. Many academic medical centers now offer multiple approaches to searching MEDLINE.

The picture becomes much less bright as you move away from the major medical centers. There are, of course, many fine libraries in hospitals throughout the country. Doctors affiliated with such hospitals also have ready access to information services. Not all hospitals have libraries, however, and cutbacks in library services are unfortunately viewed by some as an acceptable strategy for hospital cost containment. Doctors not affiliated with hospitals that have libraries - including many serving rural and minority populations - are the least likely to have ready access to current information. For this reason, NLM's Outreach Planning Panel recommended the development of specific programs to reach unaffiliated health professionals.

Question. To what degree are our local hospital and academic medical libraries technically equipped to enter this information age? What is NLM's plan in this regard?

Answer. Most hospital and many academic medical libraries need to retool to contribute more effectively to the dissemination of biomedical information. Responding to recommendations in the overall NLM Long Range Plan and the Outreach Panel report, NLM is using three mechanisms to assist in this process. These are: Information Access Grants to help hospital libraries obtain more effective information technology, the Integrated Academic Information Management Systems (IAIMS) Program grants to assist a small number of academic medical centers to transform their various information bases into an integrated system, and an expanded and revamped Regional Medical Library Network that will include programs to introduce new technologies to library managers and assist them in preparing grant applications related to the improvement of information technology.

MEDICAL LIBRARIAN TRAINING

Question. What is NLM's role in the retraining of medical librarians and in establishing professional training programs in the field of health sciences information management to prepare medical librarians for the electronic era?

Answer. Over the past 25 years, NLM has supported a variety of training and retraining programs for medical librarians through the Regional Medical Library Program, through specific training grants and at the National Library of Medicine itself. At present, NLM continues to conduct a one-year post-graduate training program to prepare librarians for responsible positions in health sciences information management. NLM is aware that the current information environment calls for new efforts to train and retrain medical librarians and is examining how it can promote such training most effectively.

OUTREACH

Question. NLM has put a high priority on its outreach efforts. What part do local medical librarians play in this?

Answer. Local medical librarians are expected to play a key role in outreach to underserved and unaffiliated health professionals in their geographic areas. In FY 1990, NLM expects to sponsor up to 20 individual library outreach projects of up to $25,000 each. Under these projects, local librarians will develop outreach strategies that seem appropriate to conditions within their communities and will evaluate the success of the methods they have chosen. The experience with these projects will provide a basis for determining how local librarians can contribute most effectively to the goals of NLM's Outreach program.

INTEGRATED ACADEMIC INFORMATION MANAGEMENT SYSTEM GRANTS

Question. What has been NLM's experience with its IAIMS (Integrated Academic Information Management System) grants program for information systems in the medical centers?

Answer. The IAIMS Program has been very successful. In initiating the IAIMS grant program in 1984, NLM's goal was to assist a limited number of institutions to achieve IAIMS implementation in order to demonstrate the IAIMS concept in operation. The concept of integrated information systems planning and development has been extremely well received by the health sciences community. With NLM's funds serving as a catalyst, the Federal investment being achieved in IAIMS activity generates a contribution ten times as much by the institution and other sources for IAIMS development. Those IAIMS that have been created and tested at a few sites with NLM support already show major improvements in knowledge accessibility and utilization. Within existing resources, in FY 1991 NLM will continue to support four institutions in the implementation of IAIMS as part of its goal to complete the model systems.

Question. Why are you no longer funding planning grants for IAIMS systems?

Answer. Present budgetary constraints require limited funding of the IAIMS program. In FY 1991, NLM will support four institutions in the IAIMS implementation phase and one in the model testing phase.

PAPERWORK REDUCTION ACT REAUTHORIZATION

Question. The Congress is scheduled to reauthorize the Paperwork Reduction Act this year, and I have begun to hear of concerns that certain reauthorization proposals would affect NLM and its information dissemination activities. Could you explain how reauthorization of the Paperwork Reduction Act will affect NLM?

Answer. There are three proposals now in Congress that would reauthorize the Paperwork Reduction Act. One reauthorization bill continues the current provisions of the Paperwork Reduction Act. It does not affect the NLM information dissemination activities. The other two proposals would expand the original Paperwork Reduction Act with new provisions that address Federal agency information dissemination activities. Of these two, the House bill, H.R. 3695, "Paperwork Reduction and Federal Information Resources Management Act of 1989" could seriously affect NLM dissemination activities.

H.R. 3695 contains provisions that would prohibit agencies from exercising controls over government data redisseminated by the public, prohibit charging fees for redistributed data, and mandate "marginal costing" for products. These provisions could have a serious impact on the NLM's quality assurance goals, and its cost recovery program. They would do this by restricting the NLM from entering into licensing agreements with vendors for privately distributed MEDLARS databases. It is under these agreements that NLM ensures the continued quality and integrity of these databases. The agreements also provide the means to recover access costs through reasonable fees. Under current policy, and existing direction of the Congressional authorization and appropriation committees, NLM with its appropriated funds pays the costs of creating the databases and the biomedical community incurs the costs, through fees, of accessing the databases. The NLM calculates these fees across all products and services with access costs recovered in the aggregate. The House bill could eliminate these current cost recovery methods for NLM with a loss of approximately $12 million in revenue a year.

AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Question. Under the 1989 legislation authorizing creation of the new Agency for Health Care Policy and Research the NLM is required to enter into an inter-agency agreement with the new agency to develop a plan for indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information. What is the status of that charge? Is funding for this project included in the 1991 appropriation request?

Answer. NLM and the Agency for Health Care Policy and Research have agreed on a general strategy for carrying out this charge and are working out the details of the interagency agreement. Start-up activities will include additional acquisitions and indexing, specific outreach directed at the health services research community, and work on the development of a full-text practice guidelines database. NLM's FY 1991 budget does not include funds to cover the cost of the new legislation, but we anticipate the transfer of funds to NLM from the new Agency in both FY 1990 and FY 1991. Beyond FY 1991, necessary funding should be included within the NLM appropriation.

NURSING SHORTAGE

Senator Harkin. Dr. Hinshaw, let me just cover briefly the nursing shortage. It has been particularly troublesome because of the decline in nursing school enrollments. I understand for the first time last year enrollment has increased approximately 5 percent?

Dr. Hinshaw. That is correct, sir.

Senator Harkin. What is the status of the nursing shortage that we have been talking about for the last few years?

Dr. Hinshaw. There is a glimmer of light at the end of the tunnel I think, as was said earlier today. However, the shortage still exists. It is a problem not of supply but of demand, given the complexity of the care that is now needed, not only in hospitals but also in home care and in nursing homes and community agencies. There are so many different locations, with differing demands, and the care is so complex now that it requires the professional kind of background which registered nurses have. So it is more of a demand issue than it is a supply issue. We are encouraged because of the upswing finally occurring in the number of enrollments in baccalaureate nursing programs across the country.

The manpower issues are handled by the Division of Nursing at HRSA, but we have approximately 6 percent of the nursing research portfolio invested in studies for retaining nurses, for building systems and environments in which they can function optimally and professionally, and which will therefore facilitate the best possible patient outcomes. The studies are focused on innovative strategies which will retain nurses within a hospital, community health or home care setting.

COMMISSION ON NURSING SHORTAGE

Senator Harkin. Last year we recommended that the Secretary appoint a nurse as an assistant to help him out in some of these regards. What is the status of that? Has that——

Dr. Hinshaw. Excuse me, Senator. There were two recommendations as I recall. One was for a new Commission on Nursing to be reestablished, and one was for a nurse at the policy level to be available for advice to the Secretary, DHHS, in terms of nursing practice issues because of the shortage.

The charter for the new Commission on the nursing shortage has now been signed, and the money has been transferred to HRSA, where the Commission will be housed with Dr. O. Marie Henry. She is the Chief Nurse Officer for the Public Health Commission Corps and is also Director of the Division of Nursing within HRSA.

I believe the feeling at this point is that the group of nurses and interdisciplinary colleagues on the Commission will serve in the advisory capacity. If additional advisory information is needed, then it will be sought from other individuals.

ANIMAL FACILITIES

Senator Harkin. Thank you.

Dr. Whitney, back to the subject I brought up today earlier today about using animals in research. As I understand it, the NIH animal facilities still do not meet accreditation standards. $18.5

million has been requested to upgrade the intramural animal facilities at NIH. Is this going to be enough?

Dr. **Whitney**. Yes, sir; I believe that if we can get that $18.5 million in fiscal year 1991, we will be able to apply for AALAC accreditation and in fact, we do intend to do that in December of this year if the appropriation comes through.

USE OF ANIMALS IN RESEARCH

Senator **Harkin**. What is going to happen with the number of research project funds that use animals? I guess about 45 percent of the grants funded now use animals. What is going to happen? Is that going to increase or decrease in the future?

Dr. **Whitney**. I would guess that the percentage would stay relatively stable. It has over the years. There are a number of nonanimal modeling techniques that are being used, but those are primarily adjuncts to the use of animal models in research. These techniques allow us to do more things, but they do not replace animals.

RHEUMATOID ARTHRITIS

Senator **Harkin**. Dr. Shulman, as you indicated, I have a great interest in the infectious disease theory of the disorder. I was visited last year by an Iowa family who had a daughter who has greatly benefited from the special treatment that follows this theory.

Senator DeConcini has also talked to me about this himself. What progress are we making on investigating the infectious disease theory of rheumatoid arthritis? Could you bring us up to date briefly on that?

Dr. **Shulman**. Yes, sir; there are several potential candidates for infectious agents as a cause of rheumatoid arthritis. One of them that interests the constituents that have seen you and Senator DeConcini are mycoplasma, one type of organism. We have been supporting research in this area, and continue to support research on mycoplasma as it relates to arthritis.

There is also great interest in certain viruses, such as Parvovirus; EB viruses are other possibilities. There is some exciting research concerning the role of chemicals that are in the walls of certain common bacteria such as a staph or strep. This chemical, which is called peptidoglycans, can induce an arthritis in experimental animals. It was developed first at North Carolina and is being explored fully by our intramural scientists who have come up with a major discovery that there seems to be a defect in the brain, the hypothalamus, in terms of the mechanism by which it promotes substances within the body to combat inflammation.

It is known as a defect of the hypothalamic-pituitary adrenal-immune axis. In other words, there may be a defect in the brain leading to susceptibility to this infectious kind of arthritis.

We are also mounting a clinical trial of minocycline, which is a tetracycline, for the treatment of rheumatoid arthritis. We have issued two requests for proposals, one for five different clinical centers to participate in it, 40 patients each; the second RFP was for a coordinating center. That we did last summer. We are now in the final stages of contract negotiations.

SUBCOMMITTEE RECESS

Senator HARKIN. I appreciate all of you for being here, and again, let me give you my personal thanks and my high esteem for all the work that you are individually and collectively doing at the NIH.

So, thank you for your excellent testimony and for the work you are doing. The subcommittee will stand in recess until 9:30 a.m., Wednesday, February 21, when we will meet in SD–192 to hear from the Department of Education.

[Whereupon, at 4:30 p.m., Tuesday, February 20, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, February 21.]

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